AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 73

2. CONTRACT (Proc. Inst. Ident.) NO.
HHSO100201600005I

3. EFFECTIVE DATE
See Block 20C

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.

5. ISSUED BY CODE HHS/OS/ASPR/BARDA

HHS/OS/ASPR/BARDA
330 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. ADMINISTERED BY (If other than Item 5) CODE ASPR-BARDA02

ASPR-BARDA
330 Independence Ave, SW, Rm G640
Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)

PROTEIN SCIENCES CORPORATION
Attn: MANON M. J. COX
1000 RESEARCH PARKWAY
MERIDEN CT 064507159

8. DELIVERY
FOB ORIGIN X OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN — ITEM

CODE 061098847 FACILITY CODE

11. SHIP TO/MARK FOR CODE

12. PAYMENT WILL BE MADE BY CODE DHHS/FMS

PSC/FMS
PSC_invoices@psc.hhs.gov

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
10 U.S.C. 2304 (c) ( ) 41 U.S.C. 253 (c) ( )

14. ACCOUNTING AND APPROPRIATION DATA
See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	18	X	J	LIST OF ATTACHMENTS	70
X	D	PACKAGING AND MARKING	30			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. X CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 2 *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (*Attachments are listed herein.*)

18. SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (*Type or print*)
Manon Cox President & CEO

20A. NAME OF CONTRACTING OFFICER
LYNDA M. BROWN

19B. NAME OF CONTRACTOR
Protein Sciences Corp.

19C. DATE SIGNED
15 Aug 2016

BY
Manon Cox
(*Signature of person authorized to sign*)

20B. UNITED STATES OF AMERICA
BY
Lynda M. Brown
(*Signature of the Contracting Officer*)

20C. DATE SIGNED
8-16-16

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 26 (Rev. 5/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

This contract incorporates by reference Protein Sciences Corporation initial offer dated February 26, 2015, additional correspondence dated July 6, 2015, November 13, 2015, March 18, 2016 and the final proposal revision dated March 17, 2016. The order of precedence will be the latest dated version for any correspondence.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. **Brief Description of Supplies or Services**

The purpose of this contract is to provide Medical Countermeasures against pandemic influenza and influenza strains with pandemic potential: Candidate Vaccine Virus stocks; Master and working virus seed for production of influenza pre-pandemic and pandemic vaccine product; Influenza pre-pandemic and pandemic vaccine small scale, clinical, commercial scale bulk lots; Adjuvant bulk at clinical and commercial scale; Vaccine and adjuvant storage and stability programs (new and existing HHS owned material); Formulation, fill and finish of pre-pandemic, pandemic influenza vaccine and adjuvant; Shipping of vaccine; Disposal of vaccine bulk and final container; Non-clinical studies; Clinical studies; BARDA Tracking Tool-Development and Testing of New Standard Data Reporting Formats.

The Statement of Work (SOW) contained in Section C provides specific details of supplies or services to be furnished.

B.2. Contract Line Item Numbers (CLINs) and Pricing:

The Contractor shall be reimbursed by the Government in an amount not less than a total of **$500,000** (minimum) and no more than a total of **$610,028,694** (maximum) if all optional CLINs are exercised.

The prices set forth in this ARTICLE B.2. will cover the Base Period **August 22, 2016 through August 21, 2019**, Option Period I – **August 22, 2019 through August 21, 2020 and Option Period II August 22, 2020 through August 21, 2021.** Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit prices (s) set forth below. Contractors shall provide the following items for the manufacturing, testing, packaging, delivery, storage and disposal of influenza MCM products.

a. Base Period: August 22, 2016 through August 21, 2019

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0001A	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	5	$136,033 (Year 1)	$680,165	
0001B	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	5	$140,114 (Year 2)	$700,570	
0001C	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	5	$144,317 (Year 3)	$721,585	$2,102,320
0002A	Influenza Vaccine Research Lot(s)	Lot	5	$350,000 (Year 1)	$1,750,000	
0002B	Influenza Vaccine Research Lot(s)	Lot	5	$360,500 (Year 2)	$1,802,500	
0002C	Influenza Vaccine Research Lot(s)	Lot	5	$371,315 (Year 3)	$1,856,575	$5,409,075
0003A	cGMP Influenza Vaccine Investigational Lot(s)	Lot	5	$412,000 (Year 1)	$2,060,000	
0003B	cGMP Influenza Vaccine Investigational Lot(s)	Lot	5	$424,360 (Year 2)	$2,121,800	
0003C	cGMP Influenza Vaccine Investigational Lot(s)	Lot	5	$437,091 (Year 3)	$2,185,455	$6,367,255

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0004A-1	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	1-2 (Year 1)	$1,964,250	$3,928,500	N/A
0004B-1	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	3-10 (Year 1)	$1,739,250	$17,392,500	N/A
0004C-1	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	11-20 (Year 1)	$1,514,250	$30,285,000	N/A
0004D-1	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	21-60* (Year 1)	$1,289,250	$77,355,000	$77,355,000
0004A-2	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	1-2 (Year 2)	$2,023,178	$4,046,356	N/A
0004B-2	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	3-10 (Year 2)	$1,791,428	$17,914,280	N/A
0004C-2	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	11-20 (Year 2)	$1,559,678	$31,193,560	N/A
0004D-2	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	21-60* (Year 2)	$1,327,928	$79,675,680	$79,675,680
0004A-3	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	1-2 (Year 3)	$2,083,873	$4,167,746	N/A
0004B-3	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	3-10 (Year 3)	$1,845,171	$18,451,710	N/A

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0004C-3	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	11-20 (Year 3)	$1,606,468	$32,129,360	N/A
0004D-3	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	21-60* (Year 3)	$1,367,766	$82,065,960	$82,065,960
0005	cGMP Adjuvant Commercial Scale Bulk Lot(s)	N/A	N/A	N/A	N/A	N/A
0006A-1	Formulation and Filling: Antigen--Single-dose vials	Each	3,333,333 (Year 1)	$3.79	$12,633,332	
0006A-2	Formulation and Filling: Antigen--Single-dose vials	Each	3,333,333 (Year 2)	$3.90	$12,999,999	
0006A-3	Formulation and Filling: Antigen--Single-dose vials	Each	3,333,333 (Year 3)	$4.02	$13,399,999	$39,033,330
0006B	Formulation and Filling: Antigen—Syringes or sprayers	Each	N/A	N/A	N/A	N/A
0006C-1	Manual Formulation and Filling: Antigen—Multi-dose vials	Each	4932 (822 MDV Per Lot/ 6 Lots Per Year)	$41.14 (Year 1)	$202,902	
0006C-2	Manual Formulation and Filling: Antigen—Multi-dose vials	Each	4932 (822 MDV Per Lot/ 6 Lots Per Year)	$42.37 (Year 2)	$208,969	
0006C-3	Manual Formulation and Filling: Antigen—Multi-dose vials	Each	4932 (822 MDV Per Lot/ 6 Lots Per Year)	$43.64 (Year 3)	$215,232	$627,103

*CLIN 0004 is a max of 60 lots per year

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0006D	Formulation and Filling: Adjuvant—Single-dose vials	N/A	N/A	N/A	N/A	N/A
0006E	Formulation and Filling: Adjuvant—Multi-dose vials	N/A	N/A	N/A	N/A	N/A
0006F	Formulation and Filling: Co-formulated antigen and adjuvant – Single dose vials	N/A	N/A	N/A	N/A	N/A
0006G	Formulation and Filling: Co-formulated antigen and adjuvant - Syringes	N/A	N/A	N/A	N/A	N/A
0006H	Formulation and Filling: Co-formulated antigen and adjuvant – Multi-dose vials	N/A	N/A	N/A	N/A	N/A
0007A-1	Storage and Stability: Investigational Lots of Antigen	Lot	7	$1,176.50 (Per Lot/ Per Month) (Year 1)	$14,118 (Per Lot/ Per 12 Months)	$98,826 (7 Lots for 12 Months)
0007A-2	Storage and Stability: Investigational Lots of Antigen	Lot	7	$1,211.80 (Per Lot/ Per Month) (Year 2)	$14,542 (Per Lot/ Per 12 Months)	$101,794 (7 Lots for 12 Months)
0007A-3	Storage and Stability: Investigational Lots of Antigen	Lot	7	$1,248.15 (Per Lot/ Per Month) (Year 3)	$14,978 (Per lot/ Per 12 Months)	$104,846 (7 Lots for 12 Months)
0007A TOTAL						**$305,466**

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0007B-1	Storage and Stability: Commercial Scale Bulk Lots of Antigen	Lot	5	$1,176.50 (Per Lot/ Per Month) (Year 1)	$14,118 (Per Lot/ Per 12 Months)	$70,590 (5 Lots for 12 Months)
0007B-2	Storage and Stability: Commercial Scale Bulk Lots of Antigen	Lot	5	$1,211.80 (Per Lot/ Per Month) (Year 2)	$14,542 (Per Lot/ Per 12 Months)	$72,710 (5 Lots for 12 Months)
0007B-3	Storage and Stability: Commercial Scale Bulk Lots of Antigen	Lot	5	$1,248.15 (Per Lot per Month) (Year 3)	$14,978 (Per Lot/ Per 12 Months)	$74,890 (5 Lots for 12 Months)
0007B TOTAL						**$218,190**
0007C-1	Storage and Stability: Antigen in Final Container	Final Container	5,000,000 SDV	$0.00774 (Per FC/ Per Month)	$0.0929 (Per FC/ Per 12 Months) $464,500 (5,000,000 FC/ Per 12 Months)	$1,393,500
0007C-2	Storage and Stability: Antigen in Final Container	Final Container	4932 MDV	$1.201 (Per FC/ Per Month)	$14.412 Per FC/Per 12 Months $71,080 (4932 FC/ Per 12 Months)	$213,240
0007D	Storage and Stability: Storage of Adjuvant bulk lots	Lot	N/A	N/A	N/A	N/A

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Estimated Dollar Value Per 12-month	Total Estimated Dollar Value (36 Month Base Period)
0007E	Storage and Stability: Storage of Adjuvant in Final Container	Final Container	N/A	N/A	N/A	N/A
0007F	Storage and Stability: Storage of licensed product	Package	N/A	N/A	N/A	N/A
0008	Shipping	Each	TBD		NTE	$9,000,000
0009	Candidate Vaccine Virus (C V V)	Each	TBD		NTE	$1,000,000
0010	Potency Reagent and Standards Manufacture and Testing	Each	TBD		NTE	$1,000,000
0011	Laboratory Testing/ Assay	Each	TBD		NTE	$1,000,000
0012	Animal Studies	Study	TBD		NTE	$400,000
0013	Clinical Studies	Study	TBD		NTE	$10,000,000
0014	Disposal of Product	Each	TBD		NTE	$10,000,000
0015	BARDA Tracking Tool- Development and Testing of New Standard Data Reporting Formats	Each	TBD		NTE	$800,000
0016	Additional Reporting	Report	NSP	NSP	NSP	NSP
Total Estimated Dollar Amount - Base Period (36 month Base Period)						**$327,966,119**

b. Option Period One: August 22, 2019 through August 21, 2020

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
0101	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	5	$148,647	$743,235
0201	Influenza Vaccine Research Lot(s)	Lot	5	$382,454	$1,912,270
0301	cGMP Influenza Vaccine Investigational Lot(s)	Lot	5	$450,204	$2,251,020
0401A	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	1-2	$2,146,389	N/A
0401B	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	3-10	$1,900,526	N/A
0401C	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	11-20	$1,654,662	N/A
0401D	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	21-60	$1,408,799	$84,527,940
0501A	cGMP Adjuvant: Clinical or Commercial Scale Bulk Lot(s)	Lot	N/A	N/A	N/A
0601A	Formulation and Filling: Antigen—Single-dose vials	Each	10,000,000	$4.1406	$41,406,000

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
0601B	Formulation and Filling: Antigen—Syringes or Sprayers	Each	N/A	N/A	N/A
0601C	Formulation and Filling (Manual): Antigen--Multi-dose vials	Each	4932 (822 MDV Per Lot/6 Lots Per Year)	$44.95	$221,693
0601D	Formulation and Filling: Adjuvant – Single dose vials	Each	N/A	N/A	N/A
0601E	Formulation and Filling: Adjuvant – Multi dose vials	Each	N/A	N/A	N/A
0601F	Formulation and Filling: Co-formulated antigen and adjuvant – Single dose vials	Each	N/A	N/A	N/A
0601H	Formulation and Filling: Co-formulated antigen and adjuvant – Syringes	Each	N/A	N/A	N/A
0701A	Storage and Stability: Investigational Lots of Antigen	Lot	7	$1,286 (Per Lot/ Per Month) $15,432 (Per Lot/ 12 Months)	$108,024

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
0701B	Storage and Stability: Commercial Scale Bulk Lots of Antigen	Lot	30	$1,286 (Per Lot/ Per Month) $15,432 (Per Lot/ 12 months)	$462,960
0701C-1	Storage and Stability: Storage of Antigen in Final Container	Final Container	5,000,000 SDV	$0.00774 (Per FC/ Per month) $0.0929 (Per FC/ Per 12 months)	$464,400
0701C-2	Storage and Stability: Storage of Antigen in Final Container	Final Container	4932 MDV	$1.201 (Per FC/ Per Month) $14.412 (Per FC/ Per 12 Months)	$71,080
0701D	Storage and Stability: Storage of Adjuvant bulk lots	Lot	N/A	N/A	N/A
0701E	Storage and Stability: Storage of Adjuvant in Final Container	Final Container	N/A	N/A	N/A
0701F	Storage and Stability: Storage of licensed product	Package	N/A	N/A	N/A
0801	Shipping	Each	TBD	NTE	$3,000,000
0901	Candidate Vaccine Virus (C V V)	Each	TBD	NTE	$300,000

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
1001	Potency Reagent and Standards Manufacture and Testing	Each	TBD	NTE	$300,000
1101	Laboratory Testing/Assay	Each	TBD	NTE	$300,000
1201	Animal Studies	Study	TBD	NTE	$100,000
1301	Clinical Studies	Study	TBD	NTE	$3,000,000
1401	Disposal of Product	Each	TBD	NTE	$10,000
1501	BARDA Tracking Tool-Development and Testing of New Standard Data Reporting Formats	Each	TBD	NTE	$250,000
1601	Additional Reporting	Report	N/A	NSP	NSP
1701A	Prior Contracts: Storage and Stability of Bulk Lots – Antigen	Lot	N/A	N/A	N/A
1701B	Prior Contracts: Storage and Stability in Final Container – Antigen	Final Container	N/A	N/A	N/A
1701C	Prior Contracts: Storage and Stability of Bulk Lots – Adjuvant	Lot	N/A	N/A	N/A
1701D	Prior Contracts: Storage and Stability in Final Container – Antigen	Final Container	N/A	N/A	N/A
Total Estimated Dollar Amount – Option Period One					**$138,685,387**

c. Option Period Two: August 22, 2020 through August 21, 2021

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
1801	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	5	$153,106	$765,530
1901	Influenza Vaccine Research Lot(s)	Lot	5	$393,928	$1,969,640
2001	cGMP Influenza Vaccine Investigational Lot(s)	Lot	5	$463,710	$2,318,550
2101	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	1-2	$2,210,781	N/A
	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	3-10	$1,957,542	N/A
	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	11-20	$1,704,302	N/A
	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	21-60	$1,451,063	$87,063,780
2201	cGMP Adjuvant Commercial Bulk Lot(s)	Bulk Lot	N/A	N/A	N/A
2301A	Formulation and Filling: Antigen--Single-dose vials	Lot	10,000,000	$4.2648	$42,648,000
2301B	Formulation and Filling: Antigen—Syringes or Sprayers	Lot	N/A	N/A	N/A
2301C	Formulation and Filling (Manual): Antigen--Multi-dose vials	Each	4932	$46.30	$228,352

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
2301D	Formulation and Filling: Adjuvant--Single-dose vials	Each	N/A	N/A	N/A
2301E	Formulation and Filling: Adjuvant--Multi-dose vials	Each	N/A	N/A	N/A
2301F	Formulation and Filling: Co-formulated antigen and adjuvant - Single-dose vials	Each	N/A	N/A	N/A
2301G	Formulation and Filling: Co-formulated antigen and adjuvant-Syringes	Each	N/A	N/A	N/A
2301H	Formulation and Filling: Co-formulated antigen and adjuvant-Multi-dose vials	Each	N/A	N/A	N/A
2401A	Storage and Stability: Investigational Lots of Antigen	Lot	7	$1,324 (Per Lot/ Per Month $15,888 (Per Lot/ 12 months)	$111,216
2401B	Storage and Stability: Commercial Scale Bulk Lots of Antigen	Lot	30	$1,324 (Per Lot/ Per Month) $15,888 (Per Lot/ 12 Months)	$476,640
2401C-1	Storage and Stability: Antigen in Final Container	Final Container	5,000,000 SDV	$0.00774 Per FC/ Per Month $0.0929 Per FC/ 12 Months	$464,400

CLIN	Item Name	Unit of Issue	Estimated Maximum Quantity	Unit Price	Total Estimated Dollar Value
2401C-2	Storage and Stability: Antigen in Final Container	Final Container	4932 MDV	$1.201 Per FC/ Per Month $14.412 Per FC/ 12 Months	$71,080
2401D	Storage and Stability: Storage of Adjuvant bulk lots	Lot	N/A	N/A	N/A
2401E	Storage and Stability: Storage of Adjuvant in Final Container	Final Container	N/A	N/A	N/A
2401F	Storage and Stability: Storage of licensed product	Package	N/A	N/A	N/A
2501	Shipping	Each	TBD	NTE	$3,000,000
2601	Candidate Vaccine Virus (C V V)	Each	TBD	NTE	$300,000
2701	Potency Reagent and Standards Manufacture and Testing	Each	TBD	NTE	$300,000
2801	Laboratory Testing/Assay	Each	TBD	NTE	$300,000
2901	Animal Studies	Study	TBD	NTE	$100,000
3001	Clinical Studies	Study	TBD	NTE	$3,000,000
3101	Disposal of Product	Each	TBD	NTE	$10,000
3201	BARDA Tracking Tool- Development and Testing of New Standard Data Reporting Formats	Each	TBD	NTE	$250,000
3301	Additional Reporting	Report	TBD	NSP	NSP
Total Estimated Dollar Amount – Option Period Two					**$143,377,188**

B.3. Vendor Production Capacity

Identify turnaround time/lead time from date of order to completion/delivery required by contractor for U/I and to reach maximum manufacturing production that vendor would be able to provide U.S. Government in event of a pandemic (identify maximum production capacity).

CLIN	Item Name	Unit of Issue	Number of Days/Lead Time from date of Order to Delivery per U/I	Maximum Quantity vendor could produce in event of pandemic	Number of Days Needed from date of Order to Delivery per Maximum Quantity
0001	cGMP Influenza Vaccine Master and Working Seed Lot	Lot	50	24	220
0002	Influenza Vaccine Development Lot(s)	Lot	70	24	147
0003	cGMP Influenza Vaccine Clinical Lot(s)	Lot	45	30	210
0004	cGMP Influenza Vaccine Commercial Scale Bulk Lot(s)	Lot	45	30	210
0006A	Formulation and Filling: Antigen-Singe dose vials	Each	44	6,960,000	225
0006C	Formulation and Filling: Antigen-Multi-dose vials	Each	44	500,000	225

B.4. Schedule of Labor Category Hourly Rates for TBD CLINs

Contractors should provide a table of position titles, description of the education level attained and years of relevant experience, and hourly rates. Responses to unpriced CLINs will rely on these tables to evaluate proposed costs. For example:

Position	**Description**	**Hourly Rate**
Analyst	B, 3+ years	$40
QA-Manager	M, 12+ years	$67
Management	D, 16+ years	$168

H: High School; B: Bachelor; M: Master; D: Doctor

B.5. Analytical Laboratory Testing/Assay-CLIN0011—Pricing per Time Point

Perform stability testing and/or other testing: SRID, HPLC, SDS-Page and Western Blot

Test Methods	**SRID**	**HPLC***	**SDS-Page**	**Western Blot**
Time Points 2-8°C				
Time Zero	$1,094.23	$1,018.11	$355.86	$508.10
3 months	$1,094.23	$1,018.11	$355.86	$508.10
6 months	$1,094.23	$1,018.11	$355.86	$508.10
9 months	$1,094.23	$1,018.11	$355.86	$508.10
12 months	$1,094.23	$1,018.11	$355.86	$508.10
18 months	$1,127.06	$1,048.65	$366.54	$523.34
24 months**	$1,849.34	$1,770.94	$1,088.83	$1,245.64

*rHA size by HPLC-SEC

**The 24 month time point contains end of study documentation costs, spread among the tests

B.6 Contract Type

This is an indefinite-delivery, indefinite-quantity (IDIQ) contract for the acquisition of MCMs for pandemic Influenza preparedness and response. During the ordering period of the contract, authorized officials assigned to the contract may order, and the Contractor shall provide supplies and services at the unit prices listed above.

1. **Delivery Order and Task Order Type**
   a. Delivery orders and task orders issued under this contract will be firm-fixed price. Order instructions can be found in Section H.17.

2. **Minimum and Maximum Quantity**
   a. The minimum ordering limitation **$0** and Government guarantee under this contract is **$500,000.**

   b. The estimated maximum ordering limitation under this contract is **$610,028,694** if all CLINs are selected, to include those the base year and options periods.

Section C-Statement of Work

Medical Countermeasures for Pandemic Influenza Vaccine Preparedness and Response

C.1 BACKGROUND:

The potential for a human influenza pandemic continues to be a public health concern. Four influenza pandemics occurred over the last century. In 2009, we completed responded to the most recent pandemic caused by a H1N1 virus. Sporadic infections of humans with avian influenza viruses with high mortality (H5N1, H7N9) suggest the public is at risk for a severe influenza pandemic. An outbreak of severe pandemic influenza could cause over 60 million deaths worldwide by some estimates.

Pillar One of the National Strategy for Pandemic Influenza (2005) describes the activities to be undertaken before a pandemic to ensure preparedness. The strategy seeks to "establish domestic production capacity and stockpile of countermeasures to ensure sufficient vaccine to vaccinate front-line personnel and at-risk populations". In the Implementation Plan for the National Strategy for Pandemic Influenza (2006) two primary goals were set "(1) establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat; and (2) expansion of domestic influenza manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration". To accomplish these goals, the Federal Government established stockpiles of influenza countermeasures, as well as domestic vaccine manufacturing capacity. In addition substantial new investments were made in the advanced development of cell-culture-based influenza vaccine candidates, with a goal of establishing the domestic surge vaccine production capacity to meet the pre-pandemic stockpile and post-pandemic vaccine production goals".

On December 2009 Secretary Sebelius called for the Public Health Medical Countermeasure Enterprise Review which was issued in August 2010 and stated: "The ultimate goal of this review is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. In other words, we want to create a system that can respond to any threat at any time"

Vaccination remains the primary countermeasure against pandemic influenza. Supporting the need for ongoing acquisition of novel subtypes of influenza, currently licensed vaccines for influenza are virus subtype specific. It remains uncertain which influenza subtype will cause the next pandemic. As a result, the ability of vaccines in the National Pre-pandemic Influenza Vaccine Stockpile to protect against emerging strains of influenza is unknown.

The current contracts for "Acquisition of MCMs for Pandemic Influenza Preparedness and Response" awarded in 2012 to five manufacturers expire in September 2015. It is critical, therefore to award contracts to manufacturers for this program in order to guarantee continuity of the pandemic influenza preparedness and response capabilities and to maintain current stockpiled vaccines and adjuvants.

The 2009 H1N1 influenza pandemic demonstrated how crucial it is to have active contracts with manufacturers to respond to an influenza pandemic event; in 2009 the Federal Government rapidly modified existing stockpile contracts and issued task orders to manufacturers to produce millions of doses of H1N1 influenza vaccine.

This program will serve as a continuation and expansion of the US Pandemic Preparedness Plan which currently includes contracts with five influenza vaccine experienced companies. The competition will be open to companies that are currently licensed for inactivated, recombinant and live attenuated influenza vaccine (LAIV), both

seasonal and pandemic. In addition, competition is open to Contractors that demonstrate a successful experience in the manufacturing of influenza vaccines at commercial scale, have completed Phase 3 clinical studies (including a final Clinical Study Report) for influenza vaccines with a documented US BLA in preparation for an influenza vaccine.

C.2.1. SCOPE OF WORK:

Independently and not as an agent of the US Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described below.

The Contractor shall:

1) Provide Medical Countermeasures (MCMs), such as vaccines, for Pandemic Influenza Preparedness and Response or as required in response to a HHS designated Public Health Emergency.

2) Produce vaccines against influenza and influenza strains with pandemic potential;

3) Vendor must:

- Hold a US influenza vaccine license **OR**
- Have developed an influenza vaccine as evidenced by:
    - A pivotal Phase 3 final clinical study report **AND**
    - Official Minutes from an US FDA Pre-BLA meeting

C.2.2. Detailed Description of Contract Line Item Numbers (CLINs):

Note: Numbers referenced for CLINs below reflect numbers identified for base period of performance for any resultant contract. CLINs will differ for option periods with item name and scope unchanged.

CLIN 0001: cGMP Influenza Vaccine Master and Working Seed Lot

The Contractor shall provide yield optimized **master and working seed lots** for inactivated, live attenuated or recombinant influenza vaccine product.

The Contractor shall:

- Manufacture Master and Working seeds lots for influenza vaccine using the same facilities, systems, equipment, processes and testing as those described and referenced in the FDA-licensed influenza vaccine or as described in the BLA in preparation, according to current Good Manufacturing Practices (cGMP) as applicable and store at appropriate conditions during lot release testing.
- Manufacture the seed lot using the qualified influenza candidate vaccine virus (CVV) reference strain as specified by HHS.
- Provide seed lot testing results in accordance to specifications as requested by FDA as part of the FDA-licensed influenza product, or the in-process BLA filing.
- Provide seed lot samples to the FDA for identity verification, and other testing as specified by HHS.
- Store seed lots according to FDA cGMP guidelines.
- Conduct stability and other testing as appropriate or specified by HHS.
- Add manufactured seed lots to ongoing inventory reports and controlled storage.

- Submit standard data report 'MN001' according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0002: Influenza Vaccine Research Lot(s)

The Contractor shall provide an influenza vaccine **small scale, research lot**.

The Contractor shall:

- Prepare a research lot as directed by HHS and specified in the RTOR.
- Provide data derived from the manufacturing process.
- Provide a final report including, at minimum, the information in the Final Report Requirement Table 1.

CLIN 0003: cGMP Influenza Vaccine: Investigational Lot(s)

The Contractor shall provide influenza vaccine **investigational lot(s)**.

The Contractor shall:

- Manufacture the clinical vaccine lot in manufacturing facilities according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or BLA under preparation.
- Perform lot release product testing of the influenza vaccine using lot release specifications of the FDA-licensed influenza vaccine product or described in the BLA document in preparation. Provide results to HHS.
- Make batch records available for review by HHS.
- Set aside samples for stability testing up to 120 months.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by HHS.
- Upon Request, submit standard data reports according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0004: cGMP Influenza Vaccine: Commercial Scale Bulk Lot(s)

The Contractor shall provide **influenza vaccine bulk** product.

The Contractor shall:

- Manufacture the commercial scale bulk vaccine lot in manufacturing facilities according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or BLA under preparation.
- Perform lot release product testing of the influenza vaccine including potency using lot release specifications of the FDA-licensed influenza vaccine product or described in the BLA document in preparation. Provide results to HHS.

- Set aside samples for stability study testing for up to 120 months. Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.
- Conduct lot release product testing of the influenza bulk vaccine according to the licensed (or in-process BLA documented) product. Provide results to HHS. Make batch records available for review by HHS.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by HHS
- Submit standard data report 'MN004' according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0005: cGMP Adjuvant: Clinical or Commercial Scale Bulk Lot(s)

The contractor shall provide **adjuvant** bulk product suitable for formulation and filling. Proposed adjuvant shall have completed Phase 2 development in combination with a pandemic or pre-pandemic antigen. Clinical evidence of antigen sparing and/or adjuvant benefit for the pandemic or pre-pandemic antigen is required.

The Contractor shall:

- Manufacture the bulk adjuvant product at clinical or commercial scale according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing.
- Make available batch records for review by HHS.
- Set aside samples for stability study testing for up to 120 months Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.
- Execute lot release product testing of bulk adjuvant.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by HHS.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0006: Formulation and Filling

The unit for this item is **each** (vial, syringe and sprayer)

The contractor shall:

- Formulate and fill influenza antigen and/or adjuvant in final containers specified in CLIN 0006 A-H.
- Formulation, fill-finish activities of vaccine and/or adjuvant shall be carried out at facilities in compliance with FDA-cGMP guidelines and if applicable, in accordance with the formulation and filling requirements that apply to FDA-licensed influenza vaccine product unless otherwise requested, specified and approved by HHS.
- Formulate material at the concentration or dosage determined by HHS.
- Fill each unit to a volume determined by HHS.

- Assure compliance of formulation and filling activities with the license or in-process BLA documentation as required by HHS.
- Assure compliance of filling activities with relevant FDA cGMP guidelines.
- Execute lot release product testing of the final container using lot release specifications of the FDA-licensed influenza vaccine product or in-process BLA.
- Affix labels onto filled final containers with HHS approved text. HHS will require coding on primary containers and secondary packages for product identification, serialization, lot number and expiration dating in accordance with FDA and GS1 / ISO standards.
- Package filled and labeled final containers as required/specified by HHS.
- Set aside final containers for stability study testing for up to 120 months. Selection of lots for stability testing will be determined after manufacture is complete and should be approved by HHS.
- Submit standard data report 'MN007' according to instructions in 'Reporting Requirements'. Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0006A: *Antigen: Single dose vials*

CLIN 0006B: *Antigen: Syringes or sprayers*

CLIN 0006C: *Antigen: Multi-dose vials*

CLIN 0006D: *Adjuvant: Single dose vials*

CLIN 0006E: *Adjuvant: Multi-dose vials*

CLIN 0006F: *Co-formulated antigen and adjuvant: Single dose vials*

CLIN 0006G: *Co-formulated antigen and adjuvant: Syringes*

CLIN 0006H: *Co-formulated antigen and adjuvant: Multi-dose vials*

CLIN 0007: Storage and Stability

The Contractor shall:

- Provide temperature controlled storage at the Contractor site approved by HHS, according to cGMP and the Contractor's product specifications.
- Store bulk lots and final containers physically segregated from other products
- Ensure proper labeling of stored materials as USG property.
- Execute stability testing of stored material in a manner consistent with the stability testing plan approved by HHS. Report interim data and results to HHS on a monthly basis.
- Ensure sufficient representative samples are available at the time of 'Storage and Stability' task order award for stability testing for 120 months from the date of manufacture.
- Ensure stored materials are compliant with the Contractor's internal quality control system and are ready for use in further cGMP governed manufacturing of clinical material or licensed doses as directed by HHS.
- Provide the government access to review the security system in place and request updates as needed.

- Include in monthly report inventory (lot number, number of lots, number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).
- Ensure that material being relocated for the contractors' convenience is adequately insured at no cost to the government and with CO approval.
- Conduct testing necessary to ensure continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
- Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
- If using a subcontracted storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by HHS.
- Submit standard data reports 'MN014' and 'MN017' according to instructions in 'Reporting Requirements'.
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0007A: Storage of investigational lots of antigen

The unit for this item is a **lot,** which equals storage and stability for one (1) lot/month.

CLIN 0007B: Storage of commercial scale bulk lots of antigen

The unit for this item is a **lot,** which equals storage and stability for one (1) lot/month.

CLIN 0007C: Storage of antigen in final container

The unit for this item is a **final container** which equals storage and stability for a single (1) final container/month.

CLIN 0007D: Storage of clinical/commercial scale lots of adjuvant

The unit for this item is a **lot** which equals a single (1) month of storage and stability for a single (1) lot/month.

CLIN 0007E: Storage of adjuvant in final container

The unit for this item is a **final container** which equals storage and stability for a single (1) final container/month.

CLIN 0007F: Storage of licensed product in final package

The unit for this item is a **package,** which equals storage and stability for a single (1) package/month.

CLIN 0008: Shipping

The unit for this item is **each** (any unit of issue contained in this SOW)

The Contractor shall:

- Package, handle and ship material to the destination specified in the RTOR.
- Arrange for transit, delivery and insurance of material shipped. Send EDI 856 Advanced Shipping Notices upon request.
- Be responsible for delivering material shipped in a condition fit for its intended use.

- Provide program and contracting offices with (transportation document (e.g. bill of lading and associated documents) upon request.
- Submit standard data report 'DM002' according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.
- Complete Attachment 2: BARDA Request For Shipment to Clinical Study Sites

CLIN 0009: Candidate Vaccine Virus (CVV)

The Contractor shall:

- Prepare non-GLP and/or GLP influenza candidate vaccine viruses using high yield donor viruses or genes as directed by HHS and specified in the RTOR.
- Perform characterization and provide results of *in vitro* and *in vivo* bio-safety level testing as necessary and specified in the RTOR.

CLIN 0010: Potency reagent and standards manufacture and testing

The Contractor shall provide influenza vaccine reagents and standards.

The Contractor shall:

- As directed by HHS, execute activities related to reagent and standards manufacture and testing including purified HA for antibody production, primary liquid standard antigen reference, secondary antigen reference and antibody production.
- As directed by HHS and specified in the RTOR, develop and produce influenza vaccine reagents and standards for other reagent process (HPLC, Mass Spec and others)
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0011: Analytical Laboratory Testing/Assay

The contractor shall:

- Conduct laboratory testing/assay as required by HHS and specified in the RTOR
- Provide costs for testing as described in the Technical/Business Proposal Instruction for CLIN0011.
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0012: Non-Clinical Studies

The Contractor shall:

- Conduct non-clinical studies as required by HHS and specified in the RTOR.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements'
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0013: Clinical Studies

The Contractor shall:

- Conduct Clinical studies as required by HHS and specified in the RTOR.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements'. Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.
- Post-Use Monitoring Data to be collected on the use of the product from other MCM access mechanisms (expanded access or EUA) as required by HHS and specified in the RTOR.
- Upon request, provide serum/tissue aliquots to HHS as directed by HHS for immunological evaluation

CLIN 0014: Disposal of product

The unit for this item is **each (lot, vial and package)**

The Contractor will dispose of all products related to this contract, as required by the USG.

The Contractor shall:

- Dispose of product following all federal and state regulations for the appropriate waste category; hazardous waste (thimerosal-containing vaccines), regulated medical waste (LAIV), solid waste (non thimerosal-containing vaccine, non LAIV).
- Provide documentation and reports on the performed and completed disposal activity.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements'.
- Provide a final report including, at minimum, the information identified in the final report requirements table.

CLIN 0015: BARDA Tracking Tool-Development and Testing of New Standard Data Reporting Formats

The Contractor shall:

- Plan and create new data sets for submission to the BARDA Tracking Tool (BTT) as described by contract and/or RTOR. These are additive to the data sets identified in Section F 'Reporting Requirements and Deliverables' For planning purposes, BARDA is considering the following data sets for evaluation and testing with the BARDA Tracking Tool and may add other data sets in the future.

Data Set	Description	Aligns with CLIN #
MN005	Production of Bulk Adjuvant Lots	CLIN #0005
MN008	Formulation, Fill and Finish of Adjuvant Lots	CLIN #0006D and 0006E
MN009	Storage of Bulk Drug Substance	CLIN #0007B
MN010	Storage of Bulk Adjuvant Lots	CLIN #0007D
MN012	Storage of Clinical Lots	CLIN #0007A
MN013	Storage of Final Drug Product	CLIN #0007E and 0007E
MN018	Storage of Master Seed	CLIN #0001
DS002	Disposal of Bulk Drug Substance	CLIN #0015
DS006	Disposal of Final Drug Product	CLIN #0015

- Conduct testing and validation of new data sets submitted to the BARDA Tracking Tool (BTT) Program as described by contract and/or RTOR. Guidance and instructions regarding new data sets (types of data, what to submit, when to submit, how to submit, frequency of submission) will be provided in the RTOR.

- Upon validation, submit new data set on a recurring basis to the BTT for all materials that are currently under contract and/or incorporated from previous contracts. New data sets, upon validation, become part of Standard Data Report baseline.
- For additional information on the current baseline requirements please review Section F 'Reporting requirements and Deliverables'.

CLIN 0016: Additional Reporting

The Contractor shall:

- Submit inventory reports, monthly progress reports, executive summaries, Government Property reports, *ad hoc* reports of urgent developments related to this program and a final report as described in detail in the Reporting Requirements and Deliverables. Provide a final report including, at minimum, the information identified in the final report requirements table.
- In Q1 of each calendar year, submit an updated table describing facility availability to complete all CLIN activities throughout the year. A template will be provided by the CO for completion.
- Respond to information requests from HHS pertaining to the ongoing activities.
- Inform the CO and COR of all issues involving any of the material managed under this contract within three (3) business days of the incident. An impact assessment and remediation plan shall be provided within twenty (20) business days of the incident.
- Provide copies of reports from regulatory inspections of facilities proposed under this contract for the completion of CLIN work to the CO and COR within five (5) business days of the inspection or receipt of the report. Provide warning letters to the CO and COR within five (5) business days of receipt.
- Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses. Submit documentation of regulatory update(s) with the monthly report.
- Provide regulatory documentation as required by HHS.

CLIN 0017: *Storage and Stability of materials from prior contracts*

The Contractor shall:

- Provide temperature controlled storage at the Contractor site approved by HHS, according to cGMP and the Contractor's product specifications.
- Store bulk lots and final containers physically segregated from other products
- Ensure proper labeling of stored materials as USG property.
- Execute stability testing of stored material in a manner consistent with the stability testing plan approved by HHS. Report interim data and results to HHS on a monthly basis.
- Ensure sufficient representative samples are available at the time of 'Storage and Stability' task order award for stability testing for 12 months from the date of manufacture.
- Ensure stored materials are compliant with the Contractor's internal quality control system and are ready for use in further cGMP governed manufacturing of clinical material or licensed doses as directed by HHS.
- Provide the government access to review the security system in place and request updates as needed.

- Include in monthly report inventory (lot number, number of lots, number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).
- Ensure that material being relocated for the contractors' convenience is adequately insured at no cost to the government and with CO approval.
- Conduct testing necessary to ensure continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
- Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed doses.
- If using a subcontracted storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by HHS.
- Submit standard data reports 'MN014' and 'MN017' according to instructions in 'Reporting Requirements'.
- Provide a final report including, at minimum, the information identified in the Final Report Requirements Table 1.

CLIN 0017A: Storage of bulk lots of antigen
The unit for this item is a **lot,** which equals storage and stability for one (1) lot/month.

CLIN 0017B: Storage of antigen in final container
The unit for this item is a **final container** which equals storage and stability for a single (1) final container/month

CLIN 0017C: Storage of bulk lots of adjuvant

The unit for this item is a **lot** which equals a single (1) month of storage and stability for a single (1) lot/month

CLIN 0017D: Storage of adjuvant in final container

The unit for this item is a **final container** which equals storage and stability for a single (1) final container/month.

C.2.3. Additional Requirements

Alternative potency assays may be used when CBER reagents are not available and must be approved by the CO. When reagents become available, potency determination should be bridged to SRID testing. Parallel testing with both assays shall continue for the duration of the stability program to document comparability. Where appropriate and requested by HHS, such comparability documentation may be submitted to FDA to evaluate feasibility of alternate potency testing for lot release under 21 CFR 610.9 Equivalent Methods and Processes.

When a Contractor manufacturers outside the US, manufactured material shall be shipped to the US within 60 days of lot release. An exception to this requirement may be requested from HHS. Shipment of the vaccine and/or adjuvant to the US shall be coordinated with HHS and other offices/agencies involved in importation of vaccines. Importation of bulk vaccine and adjuvant into the US may require testing which shall be performed according to applicable federal guidelines (e.g., FDA, USDA, and/or CDC). The Contractor shall bear all costs for shipping and testing required for import into the US. This requirement can be unilaterally modified by HHS during a public health emergency to allow for international formulation and filling prior to

shipment to the US. If the contractor has domestic/international facilities for primary and secondary manufacturing or storage, products must be shipped from/to different facilities at no cost to the US government.

Bulk manufacturing facilities shall be in compliance with appropriate biosafety level bio-containment procedures.

Contractors holding a US license for an influenza vaccine shall perform all activities described in the CLINs according to those of their FDA-licensed influenza vaccine product processes, including but not limited to the same facilities, systems, equipment processes and testing as for the licensed product. In lieu of a licensed processes, Contractors with unlicensed influenza vaccine products that have completed the final clinical study report for their Phase 3 trial and are preparing the BLA shall perform all activities described in the following CLINs using the same facilities, systems, equipment, processes, and testing as those described in the BLA document in preparation. Only Contractors without a licensed influenza vaccine may use unlicensed processes to perform work described in the CLINs. Contractors that receive licensure during the course of this contract are required to use the licensed processes for the duration of the contract and to ensure that materials previously purchased by Gov't from vendor prior to license are compliant with the licensed process, to the extent practical or reasonable with HHS approval.

Products manufactured and stored under this contract are 'Government Furnished Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.

When appropriate, Contractors shall use the same validated facilities, systems, equipment, and manufactured processes for cGMP manufacturing of licensed influenza vaccine and adjuvant product or influenza vaccine and adjuvant product with an in-process BLA.

When appropriate, Contractors shall use the same validated and approved assays and equipment for lot release of influenza vaccine product and final container influenza vaccine products and stability studies.

When appropriate, Contractors shall use the same validated facilities, systems, and equipment suitable for cGMP storage of influenza vaccine and adjuvant products.

When appropriate, contractors shall use the approved facilities, equipment, and policies to receive, store, utilize, and dispose of bio-hazardous materials in appropriate conditions (e.g. Biosafety Level 2+ as appropriate).

As appropriate, Contractors shall employ approved biosafety measures compliant with WHO biosafety guidelines for influenza vaccine including protective garments, equipment, sufficient monitoring to assure safe handling of potentially hazardous materials for the safety and protection of workers. Contractors shall conduct work under the contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions.

Notification shall be given to US Government prior to any disposal of material, records, documentation, and/or reports for consultation and disposition.

The Contractor shall allow HHS-designated personnel including BARDA staff to perform on-site auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS.

Upon request from HHS, HHS staff and/or designees will be on the Contractor's site to monitor daily activity and progress under the terms of the contract and facilitate discussion between the Contractor and HHS.

Contractors must submit documents as requested by HHS to support the preparation of a pre-EUA document for their vaccine or adjuvant.

Section D-Packaging, Marking, Shipping

D.1. SHIPPING

METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, delivery of items, e.g., reports, documents, invoices, etc. not stored by the contractor under this contract, to be furnished to the government under this contract (including invoices), shall be made by United States Postal Service mail delivery, overnight mail delivery or courier service.

Deliveries via the United States Postal Service (USPS):

Tasha McMillian, Contracting Officer
ASPR – AMCG
330 Independence Avenue SW, Room G640
Washington, D.C. 20201

Deliveries via Courier, e.g., UPS, FedEx

Tasha McMillian, Contracting Officer
ASPR-AMCG-202-205-1502
200 C St, SW
Washington, D.C. 20024

D.2. PREPARATION OF VACCINES FOR TRANSPORT

All materials shall be labeled and packaged in accordance with GCP (Good Clinical Practices) and/or GMP (Good Manufacturing Practices) as appropriate. Products hall be packed to ensure compliance with known product stability requirements that maintain satisfactory product temperatures during transit and arrival at destination. Products shall be packed to ensure maintenance of FDA recommended temperature during transit and safe arrival at destination. Freeze Watch Indicators (FWI) or equivalent temperature indicating devices shall be packed in each container containing influenza vaccine. The Contractor is required to maintain records that document the date of delivery receipt, and that the vaccine was properly maintained within the recommended cold chain temperatures during transit and receipt.

Concurrence on planned shipment protocols shall be obtained from HHS prior to transport.

Section E-Inspection and Acceptance

E.1. INSPECTION AND ACCEPTANCE

The CO or the duly authorized representative (who for purposes of this contract will be the COR) will perform inspection and acceptance of materials and services to be delivered under the contract.
Upon receipt of Final Report and inspection (physical or representative, i.e., pictures), the COR will review and recommend acceptance or rejection; the CO will correspondingly notify the Contractor of acceptance or rejection. If applicable, a task order for the storage of product shall be issued. Any product produced or stored under this contract shall be subject to inspection by the CO and the COR.
Inspections of material created under this contract may be made by a duly authorized US Government representative, and with reasonable notice (i.e., not less than 24 hours). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this contract and all records related to the manufacture, testing and storage of the product.

E.2. FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. Also, the full text of a clause may be accessed electronically at http://farsite.hill.af.mil/.

FAR Inspection Clauses Incorporated by Reference
FAR 52.246-1 - Contractor Inspection Requirements Apr 1984
FAR 52.246-2 - Inspection of Supplies – Fixed Price Aug 1996
FAR 52.246-4 – Inspection of Services – Fixed Price Aug 1996

52.246-16 – Responsibility for Supplies (Apr 1984)

(a) Title to supplies furnished under this contract shall pass to the Government upon formal acceptance, regardless of when or where the Government takes physical possession, unless the contract specifically provides for earlier passage of title.

(b) Unless the contract specifically provides otherwise, risk of loss of or damage to supplies shall remain with the Contractor until, and shall pass to the Government upon --

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Acceptance by the Government or delivery of the supplies to the Government at the destination specified in the contract, whichever is later, if transportation is f.o.b. destination.

(c) Paragraph (b) of this section shall not apply to supplies that so fail to conform to contract requirements as to give a right of rejection. The risk of loss of or damage to such nonconforming supplies remains with the Contractor until cure or acceptance. After cure or acceptance, paragraph (b) of this section shall apply.

(d) Under paragraph (b) of this section, the Contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.

Section F-Deliveries and Performance

F.1. ORDERING PERIOD AND PERIOD OF PERFORMANCE

a. The period of contract performance of this contract is a base period of thirty-six (36) months: **August 22, 2016 through August 21, 2019**.

b. If the Government exercises its option(s) pursuant to the OPTION CLAUSE Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Duration/Performance Period
Option 1	12-month – Year Four
Option 2	12-month – Year Five

F.2. PLACE and METHOD of DELIVERY

a. The delivery of the items under this contract and related supplies shall be F.O.B. Destination.
b. The place and time of delivery shall be negotiated within individual Task Orders.

F.3. REPORTING REQUIREMENTS AND DELIVERABLES

The Contractor(s) shall submit to the Contracting Officer (CO) and the Contracting Officer's Representative (COR) 1) executive summaries, 2) technical progress reports, and 3) Standard Data Submission covering the work accomplished during each monthly reporting period. By the expiration date of any issued task order(s), the Contractor shall submit a comprehensive draft and revised Final Report.

Reports shall be submitted electronically via e-mail to the COR, CO and any others they designate. One original hard copy shall be submitted to the CO. Any attachments to the e-mail report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft Project or Microsoft PowerPoint or other file types compatible with the Microsoft Office suite of products. Specialized files can be submitted with prior discussion.

1) Monthly Executive Summary:

On the fifteenth (15th) of each month for the previous calendar month the Contractor shall submit a Monthly Executive Summary to the COR and the CO. A copy of the summary will also be sent to the following email address: BardaTrackingToolInfo@hhs.gov. The executive summary will be formatted as a Microsoft Power Point presentation and will include the following:

- title page containing executive title
- the contract number and title
- the period of performance or milestone being reported
- the contractor's name and the date of submission
- project progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets
- and project issues presented headings and each item as a talking point bullet.

2) Monthly Technical Progress Reports:

On the fifteenth (15th) of each month the Contractor shall submit a report to the COR and the CO describing work accomplished in the previous calendar month. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. Technical Progress Reports will include baseline and updated project timelines, milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail to the COR, CO and the following email address: BardaTrackingToolInfo@hhs.gov. Such reports shall include the following specific information:

Title page- containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Introduction/Background - An introduction covering the purpose and scope of the contract effort.

Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period.

Task Orders - Discuss each open Task Order; describe the technical progress and issues.

Issues - Issues resolved, new issues and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned are to be furnished. Revised timelines are provided.

Contractual Issues- Include an updated table of contractual issues with columns for Issue Number, Task Order, Issue Description, Date of Initial Request, Impact, Status/Comment.

Invoices – Summary of any invoices submitted during the reporting period. Include an updated table with columns for Invoice number, Date Submitted, Amount, Activity/Comments and Date paid. The summary invoice table should include all invoices to date of the report.

Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.

Summary - Include an updated table with columns for Task Order, Description, Period of Performance and Current Status. The summary table should contain all task orders since award

Distribution List – A list of persons receiving the Technical Progress report.

Attachments – Results on the project are provided as attachments.

3) Standard Data Submissions:

Standard Data Submissions is the electronic transfer of manufacturing and supply chain data sets from the contractor’s automated information management systems or other data sources and files directly to a secure data capture system known as the BARDA Tracking Tool.

The Contractor(s) shall submit the following data sets to the BARDA Tracking Tool within three months of award.

Data Set Number	Description	Aligns with CLIN #
MN001	Seed Development, Selection and Production	CLIN #0001
MN004	Production of cGMP Bulk Drug Substance	CLIN #0004
MN007	Formulation, Fill and Finish of Final Drug Product	CLIN #0006
MN014	Stability Information / Studies of Bulk Drug Substance	CLIN #0007
MN017	Stability Information / Studies of Final Drug Product	CLIN #0007
DM002	Domestic Shipment of Final Drug Product	CLIN#0008

Instructions for connecting with the BTT will be provided at Contract Award.

Instructions for preparing data sets are defined under BARDA Tracking Tool.

New data sets will be communicated in future 'Requests for Task Order Response' under CLIN 15.

4) **Monthly Teleconference** – A monthly teleconference to review the content of the written monthly report. The Contractor shall provide minutes for the monthly teleconference with the next monthly report.

5) **Task Order Final Report and Contract Final Report–** By the expiration date of each individual Task Order and contract, the Contractor shall submit a comprehensive Final Report that shall detail, document, and summarize the results of the entire Task Order and contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the CO for the COR to review and provide comments. Next, the original, and an electronic file containing the Final Report with revisions shall be submitted to the CO for distribution to the COR. Provide the information identified in Table 1: Task Order Final Report Requirements.

Final Report Requirements Table 1:

	CLIN 0001 MVS/WVS	CLIN 0002 Research Lot(s)	CLIN 0003 Investigational Lots	CLIN 0004 Antigen Commercial Scale Bulk lot(s)	CLIN 0005 Adjuvant Clinical/Commercial Scale lot(s)	CLIN 0006 Formulation and filling	CLIN 0007 Storage and Stability	CLIN 0008 Shipping	CLIN 009 Candidate Vaccine Virus	CLIN 0010 Potency Reag. and Stand. Mnfcg and Testing	CLIN 0011 Analytical Laboratory Testing	CLIN 0012 Non-clinical Testing	CLIN 0013 Clinical Tests	CLIN 0014 Disposal of product	CLIN 0015 Standard Data Submissions	CLIN 0016 Additional Reporting
Manufacturing location (building, room, city/country)	x	x	x	x	x	x	x		x	x						
Dates of major manufacturing steps	x	x	x	x					x	x						
Major process inputs (# eggs, bioreactor size/working volume, cell bank#, CVV, MVS/WVS, lot number)	x	x	x	x	x	x	x		x	x						
Volume (volume produced, lot size, quantity/number)	x	x	x	x	x	x				x						
Antigen yields (e.g. µg/ml, ffu/ml))		x	x	x		x				x						
Manufacturing deviations	x	x	x	x	x	x			x							
Certificates of Analysis (in English)	x	x	x	x		x										
CBER Identity certification letter	x															
Storage location and inventory (building, room, refrigerator, shelf)	x	x	x	x	x				x	x						
Pictures of produced material clearly marked with an appropriate US Government Property label	x	x	x	x	x	x										
Final Pre-Clinical Study Report												x				
Final Clinical Study Report													x			
Clinical Study Database													x			
CBER Lot release letter for licensed products				x												
Stability or other testing results	x	x	x	x	x	x	x		x		x					
Final report at the end of the POP	x	x	x	x	x	x	x	x	x	x	x	x		x		

BARDA TRACKING TOOL: Instructions for Preparing and Submitting Standard Data Sets

Standard Data Submissions refers to the electronic transfer of manufacturing and supply chain data sets from the contractor's automated information management systems or other data sources directly to another automated information management system. BARDA's information management system is automated. Submission of data to BARDA's system will be done through secure file transfer protocol (sFTP). Data submission can be done manually or automatically, depending on the contractor's preference and capability. Similarly, in most cases data will be able to be automatically generated from a contractor's system. The BARDA Tracking Tool will go through a testing phase to ensure appropriate handover of data from contractors. BARDA's secure data capture system is known as the BARDA Tracking Tool or BTT.

The BTT capitalizes on the lessons learned from the 2009 H1N1 Pandemic Influenza campaign during which extensive manual effort and precious time was expended to communicate and manage a response. By defining and standardizing data sets that represent key elements of manufacturing and supply chain activities, BARDA aims to significantly reduce the management burden and enhance the efficiencies in communications by taking advantage of current technologies and applications.

Contractors will be expected to submit data sets as defined in the formats detailed below. These data sets form the baseline for automated reporting. New data sets that are generated through CLIN #0015 requirements become part of baseline once they are tested and validated.

Baseline Datasets

Data Set Number	Description
MN001	Seed Development, Selection and Production
MN004	Production of cGMP Bulk Drug Substance
MN007	Formulation, Fill and Finish of Final Drug Product
MN014	Stability Information / Studies of Bulk Drug Substance
MN017	Stability Information / Studies of Final Drug Product
DM002	Domestic Shipment of Final Drug Product

Submission Instructions:
In general, data set files will be transmitted to the BTT whenever there is a change or update in the data. New files will overwrite existing files such that the latest file submitted represents the most current information. The only exception to the overwrite rule are submissions for MN014 and MN017. Only new data will be reported for MN014 and MN017. All files that are submitted to the BTT will go through an error check step prior to processing. A comprehensive list of error checking/validation processes will be provided at contract award.
All data sets have primary key fields that must never be NULL. Some fields have a two-step primary key system. In these cases if certain data objects are non-null, then additional primary key fields become necessary. These details are provided for each data set.

Section G-Contract Administration Data

G.1. CONTRACTING OFFICER (CO)

a. The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

b. The CO is the only person with authority to act as agent of the Government under this contract. Only the CO has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; (5) obligate the U.S. Government; (6) obligate contract funding; or (7) otherwise change any terms and conditions of this contract.

c. No information, other than that which may be contained in an authorized modification to this contract, duly issued by the CO, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from this contract.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The USG COR(s) for this contract is Vittoria.Cioce@hhs.gov

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the CO changes in requirements; (2) assist the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.3. HHSAR 352.237-75, KEY PERSONNEL (DECEMBER 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are considered essential to the work being performed under this contract:

Manon Cox, President and CEO
Valerie Mermall, Sr. VP, CAO & Corporate Secretary
Mireli Fino, VP of Manufacturing

G.4. PAYMENT BY ELECTRONIC FUNDS TRANSFER

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer – System for Award Management (JUL 2013).

G.5. INVOICE SUBMISSIONS

The Contractor shall submit one (1) original and an electronic copy of the invoice.

INVOICE/FINANCING REQUEST INSTRUCTIONS

General: The contractor shall submit claims for reimbursement in the manner and format described herein.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement.

In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information stated below:

(a) Contractor's name, address, telephone number, point of contact
(b) Government agency name, address, telephone number, point of contact
(c) Invoice Number
(d) Date of Invoice
(e) The contract number and task order number and date of task order.
(f) Requisition number indicated on task order.
(g) Contract/task order line item number, description of goods and/or services, quantity and unit price or cost (as appropriate) and total amount.
(h) Equipment. If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain the statement indicating that no item of equipment was purchase or included a completed NIH Form entitled, "Report of Government Owned, Contractor Held Property

Number of Copies: An electronic copy sent to the following:

- PSC_Invoices@psc.hhs.gov
- Contracting Officer Representative (COR)
- Contracting Officer/Contract Specialist (CO/CS)

Additionally, one original mailed to Contracting Officer or Contract Specialist identified as administrator of the contract.

Frequency: Invoices submitted in accordance with the Payment Clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer. Invoicing for CLINS shall be done at a minimum on a quarterly basis and no greater than on a monthly basis.

Preparation and Itemization of the Invoice: The invoice shall be prepared in ink, typewriter or computer printer.

Currency: All HHS contracts will be paid in U.S. currency, as offered prices must be stated in U.S. currency as well.

G.6. PAYMENT CONDITIONS

a. The contractor may not invoice for any CLIN prior to delivery and acceptance of services and/or product.
b. Accepted product which falls into any of the following categories shall be replaced by the contractor at no cost to the USG.

1. If product does not meet any criterion outlined in this contract.

2. If product is deemed to be recalled for any reason, as outlined in the Product Recalls, Including Removal and corrections published by U.S. Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs; or based upon Chapter 7 of the Regulatory Procedures Manual of March 2007.

G.7. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the CO authorizes in the pre-award negotiation process, the acquisition of property (other than real property), this paragraph will include applicable provisions and incorporate the HHS Publication, entitled, **HHS Contracting Guide for Contract of Government Property**, available at http://www.knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm.

The contractor will be responsible for maintaining Government Property (GP) in accordance with FAR 52.245-1. The products purchased, shipped and stored under this contract are considered GP and should be appropriately stored, labeled and inventoried. As defined in FAR 45.101 and 52.245.-1 ,“Contractor-acquired property” means property acquired, fabricated, or otherwise provided by the contractor for performing a contract and to which the Government has title. “Government property” means all property owned or leased by the Government. Government property includes both Government-furnished property and contractor-acquired property. Government property includes material, equipment, special tooling, special test equipment, and real property. Government property does not include intellectual property and software.

G.8 CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the resultant contract.

Section H – Special Contract Requirements

H.1. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8, FAR Clause 52.203-12 and HHSAR 352.203-70.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.2. SALARY RATE LIMITATION, HHSAR 352.231-70 (December 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule salary levels.

(End of clause)

See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/.

(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / select Another Year at the top of the page / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

H.3. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.

H.4. SUBCONTRACTING

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, **N/A** will be part of any resultant contract award.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports
The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

2. Summary Subcontract Report (SSR)
Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the CO shall be included as a contact for notification purposes at the following email address:

Tasha.McMillian@hhs.gov

H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is HHStips@oig.hhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489, Washington, D.C.

H.6. PUBLICATION AND PUBLICITY, HHSAR 352.227-70 (December 2015)

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send a copy of each article submitted for publication to the Contracting Officer's Representative. The Contractor shall also inform the Contracting Officer's Representative when the article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

(c) The Contractor shall not reference the product(s) or service(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract.

H.7. ACKNOWLEDGEMENT OF FEDERAL FUNDING

a. Publication and Publicity
Pursuant to Section 508 of Public Law 105-78, the Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:
"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under HHSO10020160005I

b. Press Releases
Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

c. Subcontractors
Contractors shall require subcontractors to adhere to these requirements (Section H.7) for HHS acknowledgement of support.

H.8. FINAL DISTRIBUTION

The Contractor cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this contract, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:

1. The Government may elect to require shipment of the vaccine to US Government facilities or to state and local health agencies and/or other providers.

2. The Government may direct the Contractor to destroy all quantities remaining in storage per the terms of CLIN 0017.

H.9. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.10. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with **45 CFR part 46** and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with **45 CFR part 46** and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

H.11. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

H.12. NOTICE TO CONTRACTORS OF REQUIREMENTS FOR COMPLIANCE WITH THE PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm.

H.13. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.
If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of these products and such failure results in a material adverse effect on the safety, purity or potency of this product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.14. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

The Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

H.15. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:
"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.16. OPTION(s)

Unless the Government exercises its option pursuant to the FAR Clause 52.217-9, the contract will consist only of the Base Period of this contract as defined in Sections B. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in Section I of this contract, the Government may, by unilateral

contract modification, require the Contractor to perform option(s) set forth in Section B. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of the base period of the contract or any subsequent option and the price of the contract will be increased as set forth in the Schedule contained in Section B of this contract.

H.17. METHOD OF ORDERING

The Federal Acquisition Streamlining Act (FASA) requires that each awardee under a multiple award contract, such as the resultant base IDIQ contracts, be given a fair opportunity to be considered for each order in excess of $3,500, unless a statutory exception applies. All awardees will be given an opportunity to compete for task orders in excess of $3,500.

H.18. EXCEPTIONS TO THE FAIR OPPORTUNITY TO BE CONSIDERED CLAUSE

In accordance with FAR 16.505, the Contracting Officer shall give every awardee a fair opportunity to be considered for a delivery-order or task-order exceeding $3,500 unless one of the following statutory exceptions applies:

(A) The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
(B) Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
(C) The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
(D) It is necessary to place an order to satisfy a minimum guarantee under a base IDIQ contract.

H.19. TASK ORDER PROCEDURES

In providing services under this contract, the following procedures shall apply to the award of Task Orders (TO). All work required under this Indefinite Delivery Indefinite Quantity (IDIQ) contract shall be authorized through execution of an agreement, "Task Order," signed by the Contracting Officer. Task Orders may be awarded at any time within the contract period.
When the Government elects to fill a requirement that is estimated to exceed $3,500, the Contracting Officer shall provide a Request for Task Order Response (RTOR) to the IDIQ awardees for the particular CLIN(s) for which responses are being solicited. An RTOR shall, at a minimum, include a Statement of

Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.
If necessary, the Contracting Officer shall arrange a meeting between contractors and members of the sponsoring office to discuss the proposed Task Order prior to submitting RTOR proposals (technical and business). **Business proposals shall include appropriate support for all costs proposed as necessary for performing the task**. RTOR proposals shall generally be limited to twenty (20) pages, including attachments.
Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task and will be designated in each RTOR), Contractors shall submit their proposals in response to an RTOR, which shall include, but not necessarily limited to the following information:
(i) A statement that the contractor has a clear understanding of the task requirements;

(ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;
(iii) An approach to perform the work;
(iv) The labor category necessary, and the number of hours for each labor category necessary, and an explanation of the rationale for determining hours;
(v) Resumes with identification of the actual personnel proposed for the work;
(vi) A schedule of performance identifying major milestones, deliverables and delivery date, and task completion; and
(vii) An itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task Orders will be awarded to the contractor whose proposal is determined to be the most advantageous to the Government based on the technical and cost factors specified in the RTOR. The Government reserves the right to make an award on the most favorable initial proposal without discussion.

The Contracting Officer is the only individual authorized to issue an RTOR or award a Task Order under this contract. Unless specifically authorized by the Contracting Officer, the contractor shall not commence work on a requirement until a fully executed Task Order has been awarded.
It is anticipated that Task Orders will be awarded within sixty (60) calendar days from receipt of RTOR proposals. Each Task Order shall, at a minimum, contain the following information:

- Date of order
- Contract number and Task Order number sequentially
- Description of services and estimated cost
- Performance period
- Name and address of sponsoring office
- Name of Contracting Officer's Representative
- Place of performance
- Packaging and shipping instructions, if any
- Accounting and appropriation data
- Pricing Arrangements
- Any other pertinent information

Contractors are required to propose hourly rates for each labor classification in their response to each RTOR with cost reimbursable contract line items proposed for other elements of cost (i.e. fringe benefits, supplies, travel, equipment, other direct costs, indirect costs, fee, etc.) The subsequent negotiation of RTORs issued to successful contractors eligible to submit a proposal under an RTOR for which they qualify will focus on the number of hours proposed for each labor category and the estimated costs required for all other elements.

H.20. LIABILITY PROTECTION UNDER THE PREP ACT

The Secretary’s Declaration for Public Readiness and Emergency Preparedness Act (PREP Act), Section 319F-3 of the Public Health Service Act, 42 U.S.C. 247d-6d, Coverage for Vaccines Against Pandemic Influenza A Viruses and Influenza A Viruses With Pandemic Potential effective February 29, 2012 (as amended) applies to this contract subject to the terms and conditions of such Declaration and any amendments thereto.

H.21. BARDA Security Requirements

Section I. Security Administration:

1. Security Program: The contractor shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The contractor's proposal shall include a security plan which establishes security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined in Section II (noted below) by time of contract award. The contractor shall also ensure that other entities (sub-contractors, consultants, etc.) performing work on behalf of the contractor establishes and manages a security program that is in compliance with BARDA security requirements.

2. Facility Security Plan: As part of the contractor's overall security program, the contractor shall submit a written security plan (in their proposal) to the Contracting Officer to be evaluated by the Technical Evaluation Panel (TEP), which will include a member of BARDA's Program Protection Office. Performance of work under the BARDA contract will be in accordance with the contractor's approved security plan. The contractor's security plan will include the following processes and procedures at a minimum:

(a) Security Administration: Organization and responsibilities; security risk assessment for site; threat levels identification; security procedures during elevated threats; liaison with law enforcement; security education and training.

(b) Personnel Security Policies and Procedures*:* Candidate recruitment process; background investigations; employment suitability policy; access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements.

(c) Physical Security Policies and Procedures: Internal / external access control; protective services; identification/ badging; visitor access controls; parking areas and access control; perimeter fencing / barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring / response; closed circuit television; product storage security; other control measures.

(d) Information Security: Identification of sensitive information; access control; storage of information; document control; retention/ destruction requirements.

(e) Information Technology Security Policies and Procedures: Intrusion detection and prevention systems; employee training; encryption systems; identification of sensitive information/ media; password policy; removable media policy; laptop policy; media access control/ determination; secure storage; system document control; system backup; system disaster recovery.

3. Site master plan: Contractor shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; bio-containment laboratories.

4. Site threat / risk assessment: Contractor shall provide a written risk assessment for the facility addressing: criminal threat; terrorist threat; industrial espionage; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies.

Section II. Security Requirements:

1. Physical Security:

(a) **Closed Circuit Television (CCTV) Monitoring:**

- CCTV with time lapse video recording for exits / entrances to the facility and buildings where critical assets are processed and stored.
- Video recordings maintained for a minimum of 30 days.

(b) **Lighting**:

- Lighting covering perimeter, parking areas, entrances/exits. Lighting should have emergency power backup and be sufficient for CCTV.

(c) **Receiving and Shipping:**

- Receiving and shipping areas must have controlled access and contingency plans that implement modified procedures to restrict shipping and receiving to mission critical products during times of elevated threat.

(d) **Physical Access Control:**

- Intrusion Detection System with centralized monitoring system capability.
- Immediate notification / response to any alarms.
- Electronic system (i.e. card key) utilized to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, etc.)

(e) **Employee/Visitor Identification:**

- Photo identification for all personnel displayed at all times.
- Visitor control; identification; screening and accountability system.

(f) **Security Fencing:**

- Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.

(g) **Protective Security Forces:**

- Requirements for a security force at the facility will be determined by the

criticality of the program and the potential threat environment.

2. Security Operations:

(a) **Information Sharing:**

- Establish liaison with law enforcement and procedures for receiving and disseminating threat information.

(b) **Training:**

- Conduct new employee security awareness training.
- Conduct and maintain records of annual security awareness training.

(c) **Security Management:**

- Designate a knowledgeable employee to manage security operations.

3. Personnel Security:

(a) **Records Checks / Interview:**

- Verification of date of birth; citizenship; education; previous employment (5 year history); previous residences (5 year history); national / local criminal records search; and a personal interview of candidate.

(b) **Hiring / Retention Standards:**

- Policies concerning hiring and retention of employees to include employee conduct and behavior standards.

4. Information Security:

(a) **Physical Document Control:**

- Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings.
- Sensitive, proprietary and government documents should be maintained in a lockable filing cabinet / desk or other storage device.

(b) **Document Destruction**

- Documents shall be destroyed using approved destruction measures (i.e. shredders / third party vendor / pulverizing / incinerator).

5. Information Technology Security:

(a) **Access:**

- Limit information system access to authorized users.
- Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.
- Limit physical access to information systems and equipment.

(b) **Training:**

- Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to IT systems.

(c) **Audit and Accountability:**

- Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate information system activity; and ensure that the actions of individual information system users can be uniquely traced to those users.

(d) **Configuration Management:**

- Establish and enforce security configuration settings.

(e) **Contingency Planning:**

- Establish, maintain, and implement plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources.

(f) **Incident Response:**

- Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery.

(g) **Media Protection:**

- Protect information system media, both paper and digital; limit access to information on information system media to authorized users; and sanitize or destroy information system media no longer needed.

(h) **Physical / Environmental Protection:**

- Limit physical access to information systems, equipment, and the respective operating environments to authorized individuals; protect the physical and support infrastructure for information systems;
- Protect information systems against environmental hazards; provide appropriate environmental controls in facilities containing information systems.

6. Transportation Security: Adequate security controls shall be implemented to protect materials while in transit from theft, destruction, manipulation, or damage. These security measures will be addressed in the Facility Security Plan.

7. Security Reporting Requirements: The Contractor shall immediately report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.

8. Security Audits: The Contractor agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub locations.

H. 22. PRODUCT LICENSURE

Flublok® 1795

H.23. Contractor's CAGE Code, DUNS, and TIN

CAGE Code: 1EAP2 DUNS: 109124933 TIN: 06-1098847

Section I – Contract Clauses

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

FAR Clauses Incorporated by Reference
52.202-1 - Definitions (Nov 2013)
52.203-3, Gratuities (Apr 1984)
52.203-5 - Covenant Against Contingent Fees (May 2014)
52.203-6 - Restrictions on Subcontractor Sales to the Government (Sep 2006)
52.203-7 - Anti-Kickback Procedures (May 2014)
52.203-8 - Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (May 2014)
52.203-10 - Price or Fee Adjustment for Illegal or Improper Activity (May 2014)
52.203-12 - Limitation on Payments to Influence Certain Federal Transactions (Oct 2010)
52.203-13 – Contractor Code of Business Ethics and Conduct (Oct 2015)
52.204-4 - Printed or Copied Double-Sided on Recycled Paper (May 2011)
52.204-7 – System for Award Management (Jul 2013)
52.209-6 - Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Oct 2015)
52.211-5 - Material Requirements (Aug 2000)
52.215-2 - Audit and Records - Negotiation (Oct 2010)
52.215-8 - Order of Precedence - Uniform Contract Format (Oct 1997)
52.215-10 - Price Reduction for Defective Cost or Pricing Data (Aug 2011)
52.215-12 - Subcontractor Cost or Pricing Data (Oct 2010)
52.215-14 - Integrity of Unit Prices (Oct 2010)
52.215-15 - Pension Adjustments and Asset Reversions (Oct 2010)
52.215-18 - Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions (Jul 2005)

52.215-19 - Notification of Ownership Changes (Oct 1997)
52.215-21 - Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications (Oct 2010)
52.216-7 - Allowable Cost and Payment (Jun 2013)
52.216-18 - Ordering (Oct 1995)
52.216-19, Order Limitations ((Oct 1995)
52.216-22 - Indefinite Quantity (Oct 1995)
52.219-16 - Liquidated Damages – Subcontracting Plan (Jan 1999)
52.222.3 - Convict Labor (Jun 2003)
52.222-19 - Child Labor – Cooperation with Authorities and Remedies (Feb 2016)
52.222-20 -Contracts for Materials, Supplies, Articles, and Equipment Exceeding $15,000 (May 2014)
52.222-21 - Prohibition of Segregated Facilities (Apr 2015)
52.222-26 - Equal Opportunity (Apr 2015)
52.222-35 - Equal Opportunity for Veterans (Oct 2015)
52.222-36 – Equal Opportunities for Workers Disabilities (Jul 2014)
52.222-37 - Employment Reports on Veterans (Feb 2016)
52.222-50 - Combating Trafficking in Persons (mar 2015)
52.222-54 - Employment Eligibility Verification (Oct 2015)
52.223-6 - Drug-Free Workplace (May 2001)
52.225-13 - Restrictions on Certain Foreign Purchases (Jun 2008)
52.225-25 -- Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications (Oct 2015)
52.227-1 - Authorization and Consent, Alternate I (Apr 1984) (Dec 2007)
52.227-2 - Notice and Assistance Regarding Patent and Copyright Infringement (Dec 2007)
52.227-14 - Rights in Data – General (May 2014) Alternate II (Dec 2007)
52.229-3 - Federal, State and Local Taxes (Feb 2013)

52.232-1 - Payments (Apr 1984)
52.232-8 - Discounts for Prompt Payment (Feb 2002)
52.232-9 - Limitation on Withholding of Payments (Apr 1984)
52.232-11 - Extras (Apr 1984)
52.232-17 - Interest (Over $100,000) (May 2014)
52.232-23 - Assignment of Claims (May 2014)
52.232-25 - Prompt Payment (Jul 2013)
52.232-33 - Payment by Electronic Funds Transfer—System for Award Management (Jul 2013)
52.233-1 - Disputes (May 2014)
52.233-3 - Protest After Award (Aug 1996)
52.233-4 - Applicable Law for Breach of Contract Claim (Oct 2004)
52.242-13 - Bankruptcy (Jul 1995)
52.243-1 - Changes – Fixed Price (Aug 1987)
52.244-6 - Subcontracts for Commercial Items (Jun 2016)
52.245-1 - Government Property (Apr 2012)
52.246-23 - Limitation of Liability (Feb 1997)
52.249-2 - Termination for Convenience of the Government (Fixed-Price) (Apr 2012)
52.249-8 - Default (Fixed-Price Supply and Service) (Apr 1984)
52.253-1 - Computer Generated Forms (Jan 1991)

I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR, CHAPTER 3) CLAUSES:

HHSAR Clauses Incorporated by Reference
352.203-70 - Anti-Lobbying (Dec 2015)
352.270-4b - Protection of Human Subjects (Dec 2015)

352.270-5a – Notice of Offerors of equirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Dec 2015)

I.3. FAR CLAUSES IN FULL TEXT

52-203-14 Display of Hotline Poster(s) (Oct 2015)

(a) Definition.

"United States," as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

(b) Display *of fraud hotline poster(s)*. Except as provided in paragraph (c)—

(1) During contract performance in the United States, the Contractor shall prominently display in common work areas within business segments performing work under this contract and at contract work sites—

(i) Any agency fraud hotline poster or Department of Homeland Security (DHS) fraud hotline poster identified in paragraph (b)(3) of this clause; and

(ii) Any DHS fraud hotline poster subsequently identified by the Contracting Officer.

(2) Additionally, if the Contractor maintains a company website as a method of providing information to employees, the Contractor shall display an electronic version of the poster(s) at the website.

(3) Any required posters may be obtained as follows:

Poster(s)	Obtain from
HHS Contractor Code of Ethics and Business Conduct Poster	**oig.hhs.gov/fraud/reportfraud/OIG_Hotline_Poster.pdf** or see Attachment 3

(Contracting Officer shall insert—

(i) Appropriate agency name(s) and/or title of applicable Department of Homeland Security fraud hotline poster); and
(j) The website(s) or other contract information for obtaining the poster(s).)

(c) If the Contractor has implemented a business ethics and conduct awareness program, including a reporting mechanism, such as a hotline poster, then the Contractor need not display any agency fraud hotline posters as required in paragraph (b) of this clause, other than any required DHS posters.

(d) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed $5.5 million, except when the subcontract—

(1) Is for the acquisition of a commercial item; or

(2) Is performed entirely outside the United States.

(End of clause)

52.216-18 - Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from August 22, 2016 - August 21, 2019 (Base).

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

Order Limitation for contract award(s) under 15-100-SOL-00003 (in lieu of FAR 52.216-19 – Order Limitations)
(a) Minimum order limitation: $0 and Government guarantee under this contract is $500,000.00 guarantee for any resultant contract award(s).
Task/Delivery order(s) will be issued against the resultant Indefinite Delivery Indefinite Quantity contract award(s).

(b) Maximum order limitation: The maximum ordering limitation under this contract is the total estimated dollar value of this contract.
Offeror may identify maximum production capability in Offer Submission Package.

52.216-22 - **Indefinite Quantity (Oct 1995)**

(a) This is an indefinite-quantity contract for the supplies or services specified and effective for the period stated in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after task/delivery order period of performance end date.

(End of Clause)

52.217-9 - Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years.

(End of Clause)

52.219-8 -- Utilization of Small Business Concerns (Oct 2014)

(a) *Definitions.* As used in this contract--

"HUBZone small business concern" means a small business concern that appears on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration.

“Service-disabled veteran-owned small business concern”—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) “Service-disabled veteran” means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern" means a small business as defined pursuant to Section 3 of the Small Business Act and relevant regulations promulgated pursuant thereto.

"Small disadvantaged business concern, consistent with 13 CFR 124.1002,” means a small business concern under the size standard applicable to the acquisition, that--

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by--

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

“Veteran-owned small business concern” means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern" means a small business concern--

(1) That is at least 51 percent owned by one or more women, or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women**.**

(b) It is the policy of the United States that small business concerns, veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns, and women-owned small business concerns shall have the maximum practicable opportunity to participate in performing contracts let by any Federal agency, including contracts and subcontracts for subsystems, assemblies, components, and related services for major systems. It is further the policy of the United States that its prime contractors establish procedures to ensure the timely payment of amounts due pursuant to the terms of their subcontracts with small business concerns, veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns, and women-owned small business concerns.

(c) The Contractor hereby agrees to carry out this policy in the awarding of subcontracts to the fullest extent consistent with efficient contract performance. The Contractor further agrees to cooperate in any studies or surveys as may be conducted by the United States Small Business Administration or the awarding agency of the United States as may be necessary to determine the extent of the Contractor's compliance with this clause.

(d)

(1) Contractors acting in good faith may rely on written representations by their subcontractors regarding their status as a small business concern, a veteran-owned small business concern, a service-disabled veteran-owned small business concern, a small disadvantaged business concern, or a women-owned small business concern.

(2) The Contractor shall confirm that a subcontractor representing itself as a HUBZone small business concern is certified by SBA as a HUBZone small business concern by accessing the System for Award Management database or by contacting the SBA. Options for contacting the SBA include—

(i) HUBZone small business database search application Web page at http://dsbs.sba.gov/dsbs/search/dsp_searchhubzone.cfm ; or http://www.sba.gov/hubzone ;

(ii) In writing to the Director/HUB, U.S. Small Business Administration, 409 3rd Street, SW., Washington DC 20416; or

(iii) The SBA HUBZone Help Desk at hubzone@sba.gov .

(End of clause)

52.219-9 -- Small Business Subcontracting Plan (Oct 2015), Alternate II (Oct 2001).

(a) This clause does not apply to small business concerns.

(b) *Definitions*. As used in this clause—

"Alaska Native Corporation (ANC)" means any Regional Corporation, Village Corporation, Urban Corporation, or Group Corporation organized under the laws of the State of Alaska in accordance with the Alaska Native Claims Settlement Act, as amended (43 U.S.C. 1601, *et seq.*) and which is considered a minority and economically disadvantaged concern under the criteria at 43 U.S.C. 1626(e)(1). This definition also includes ANC direct and indirect subsidiary corporations, joint ventures, and partnerships that meet the requirements of 43 U.S.C. 1626 (e)(2).

"Commercial item" means a product or service that satisfies the definition of commercial item in section 2.101 of the Federal Acquisition Regulation.

"Commercial plan" means a subcontracting plan (including goals) that covers the offeror's fiscal year and that applies to the entire production of commercial items sold by either the entire company or a portion thereof (*e.g.*, division, plant, or product line).

"Electronic Subcontracting Reporting System (eSRS)" means the Governmentwide, electronic, web-based system for small business subcontracting program reporting. The eSRS is located at http://www.esrs.gov.

"Indian tribe" means any Indian tribe, band, group, pueblo, or community, including native villages and native groups (including corporations organized by Kenai, Juneau, Sitka, and Kodiak) as defined in the Alaska Native Claims Settlement Act (43 U.S.C.A. 1601 *et seq*.), that is recognized by the Federal Government as eligible for services from the Bureau of Indian Affairs in accordance with 25 U.S.C. 1452(c). This definition also includes Indian-owned economic enterprises that meet the requirements of 25 U.S.C. 1452(e).

"Individual contract plan" means a subcontracting plan that covers the entire contract period (including option periods), applies to a specific contract, and has goals that are based on the offeror's planned subcontracting in support of the specific contract except that indirect costs incurred for common or joint purposes may be allocated on a prorated basis to the contract.

"Master plan" means a subcontracting plan that contains all the required elements of an individual contract plan, except goals, and may be incorporated into individual contract plans, provided the master plan has been approved.

"Subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

(c) The offeror, upon request by the Contracting Officer, shall submit and negotiate a subcontracting plan, where applicable, that separately addresses subcontracting with small business concerns, veteran-owned small business,

service-disabled veteran-owned small business, HUBZone small business concerns, small disadvantaged business, and with women-owned small business concerns. If the offeror is submitting an individual contract plan, the plan must separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns with a separate part for the basic contract and separate parts for each option (if any). The plan shall be included in and made a part of the resultant contract. The subcontracting plan shall be negotiated within the time specified by the Contracting Officer. Failure to submit and negotiate the subcontracting plan shall make the offeror ineligible for award of a contract.

(d) The offeror's subcontracting plan shall include the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as subcontractors. The offeror shall include all subcontracts that contribute to contract performance, and may include a proportionate share of products and services that are normally allocated as indirect costs. In accordance with 43 U.S.C. 1626:

(i) Subcontracts awarded to an ANC or Indian tribe shall be counted towards the subcontracting goals for small business and small disadvantages business (SDB) concerns, regardless of the size or Small Business Administration certification status of the ANC or Indian tribe.

(ii) Where one or more subcontractors are in the subcontract tier between the prime contractor and the ANC or Indian tribe, the ANC or Indian tribe shall designate the appropriate contractor(s) to count the subcontract towards its small business and small disadvantaged business subcontracting goals.

(A) In most cases, the appropriate Contractor is the Contractor that awarded the subcontract to the ANC or Indian tribe.

(B) If the ANC or Indian tribe designates more than one Contractor to count the subcontract toward its goals, the ANC or Indian tribe shall designate only a portion of the total subcontract award to each Contractor. The sum of the amounts designated to various Contractors cannot exceed the total value of the subcontract.

(C) The ANC or Indian tribe shall give a copy of the written designation to the Contracting Officer, the prime Contractor, and the subcontractors in between the prime Contractor and the ANC or Indian tribe within 30 days of the date of the subcontract award.

(D) If the Contracting Officer does not receive a copy of the ANC's or the Indian tribe's written designation within 30 days of the subcontract award, the Contractor that awarded the subcontract to the ANC or Indian tribe will be considered the designated Contractor.

(2) A statement of—

(i) Total dollars planned to be subcontracted for an individual contract plan; or the offeror's total projected sales, expressed in dollars, and the total value of projected subcontracts to support the sales for a commercial plan;

(ii) Total dollars planned to be subcontracted to small business concerns (including ANC and Indian tribes);

(iii) Total dollars planned to be subcontracted to veteran-owned small business concerns;

(iv) Total dollars planned to be subcontracted to service-disabled veteran-owned small business;

(v) Total dollars planned to be subcontracted to HUBZone small business concerns;

(vi) Total dollars planned to be subcontracted to small disadvantaged business concerns (including ANCs and Indian tribes); and

(vii) Total dollars planned to be subcontracted to women-owned small business concerns.

(3) A description of the principal types of supplies and services to be subcontracted, and an identification of the types planned for subcontracting to --

(i) Small business concerns,

(ii) Veteran-owned small business concerns;

(iii) Service-disabled veteran-owned small business concerns;

(iv) HUBZone small business concerns;
(v) Small disadvantaged business concerns, and
(vi) Women-owned small business concerns.

(4) A description of the method used to develop the subcontracting goals in paragraph (d)(1) of this clause.

(5) A description of the method used to identify potential sources for solicitation purposes (*e.g.*, existing company source lists, the System for Award Management (SAM), veterans service organizations, the National Minority Purchasing Council Vendor Information Service, the Research and Information Division of the Minority Business Development Agency in the Department of Commerce, or small, HUBZone, small disadvantaged, and women-owned small business trade associations). A firm may rely on the information contained in SAM as an accurate representation of a concern's size and ownership characteristics for the purposes of maintaining a small, veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged, and women-owned small business source list. Use of SAM as its source list does not relieve a firm of its responsibilities (*e.g.*, outreach, assistance, counseling, or publicizing subcontracting opportunities) in this clause.

(6) A statement as to whether or not the offeror included indirect costs in establishing subcontracting goals, and a description of the method used to determine the proportionate share of indirect costs to be incurred with --

(i) Small business concerns (including ANC and Indian tribes);

(ii) Veteran-owned small business concerns;

(iii) Service-disabled veteran-owned small business concerns;

(iv) HUBZone small business concerns;

(v) Small disadvantaged business concerns (including ANC and Indian tribes); and

(vi) Women-owned small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program, and a description of the duties of the individual.

(8) A description of the efforts the offeror will make to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns have an equitable opportunity to compete for subcontracts.

(9) Assurances that the offeror will include the clause of this contract entitled "Utilization of Small Business Concerns" in all subcontracts that offer further subcontracting opportunities, and that the offeror will require all subcontractors (except small business concerns) that receive subcontracts in excess of $700,000 ($1.5 million for construction of any public facility with further subcontracting possibilities) to adopt a plan similar to the plan that complies with the requirements of this clause.

(10) Assurances that the offeror will --

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the offeror with the subcontracting plan;

(iii) Submit the Individual Subcontracting Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with the paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov . The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by the Small Business Administration as small disadvantaged businesses), women-owned small business concerns, and for NASA only, Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;

(iv) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;

(v) Provide its prime contract number, its DUNS number, and the e-mail address of the offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and

(vi) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the e-mail address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

(11) A description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing source lists; and a

description of the offeror's efforts to locate small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

(i) Source lists (*e.g*., SAM), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.

(ii) Organizations contacted in an attempt to locate sources that are small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.

(iii) Records on each subcontract solicitation resulting in an award of more than $150,000, indicating --

(A) Whether small business concerns were solicited and if not, why not;

(B) Whether veteran-owned small business concerns were solicited and, if not, why not;

(C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;

(D) Whether HUBZone small business concerns were solicited and, if not, why not;

(E) Whether small disadvantaged business concerns were solicited and if not, why not;

(F) Whether women-owned small business concerns were solicited and if not, why not; and

(G) If applicable, the reason award was not made to a small business concern.

(iv) Records of any outreach efforts to contact --

(A) Trade associations;

(B) Business development organizations;

(C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, and women-owned small business sources; and

(D) Veterans service organizations.

(v) Records of internal guidance and encouragement provided to buyers through --

(A) Workshops, seminars, training, etc., and

(B) Monitoring performance to evaluate compliance with the program's requirements.

(vi) On a contract-by-contract basis, records to support award data submitted by the offeror to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

(e) In order to effectively implement this plan to the extent consistent with efficient contract performance, the Contractor shall perform the following functions:

(1) Assist small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation by such concerns. Where the Contractor's lists of potential small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(2) Provide adequate and timely consideration of the potentialities of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns in all "make-or-buy" decisions.

(3) Counsel and discuss subcontracting opportunities with representatives of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business firms.

(4) Confirm that a subcontractor representing itself as a HUBZone small business concern is identified as a certified HUBZone small business concern by accessing the SAM database or by contacting SBA.

(5) Provide notice to subcontractors concerning penalties and remedies for misrepresentations of business status as small, veteran-owned small business, HUBZone small, small disadvantaged or women-owned small business for the purpose of obtaining a subcontract that is to be included as part or all of a goal contained in the Contractor's subcontracting plan.

(6) For all competitive subcontracts over the simplified acquisition threshold in which a small business concern received a small business preference, upon determination of the successful subcontract offeror, the Contractor must inform each unsuccessful small business subcontract offeror in writing of the name and location of the apparent successful offeror prior to award of the contract.

(f) A master plan on a plant or division-wide basis that contains all the elements required by paragraph (d) of this clause, except goals, may be incorporated by reference as a part of the subcontracting plan required of the offeror by this clause; provided --

(1) The master plan has been approved;

(2) The offeror ensures that the master plan is updated as necessary and provides copies of the approved master plan, including evidence of its approval, to the Contracting Officer; and

(3) Goals and any deviations from the master plan deemed necessary by the Contracting Officer to satisfy the requirements of this contract are set forth in the individual subcontracting plan.

(g) A commercial plan is the preferred type of subcontracting plan for contractors furnishing commercial items. The commercial plan shall relate to the offeror's planned subcontracting generally, for both commercial and Government business, rather than solely to the Government contract. Once the Contractor's commercial plan has been approved, the Government will not require another subcontracting plan from the same Contractor while the plan remains in effect, as long as the product or service being provided by the Contractor continues to meet the definition of a commercial item. A contractor with a commercial plan shall comply with the reporting requirements stated in paragraph (d)(10) of this clause by submitting one SSR in eSRS for all contracts covered by its commercial plan. This report shall be acknowledged or rejected in eSRS by the Contracting Officer who approved the plan. This report shall be submitted within 30 days after the end of the Government's fiscal year.

(h) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(i) A contract may have no more than one plan. When a modification meets the criteria in 19.702 for a plan, or an option is exercised, the goals associated with the modification or option shall be added to those in the existing subcontract plan.

(j) Subcontracting plans are not required from subcontractors when the prime contract contains the clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items, or when the subcontractor provides a commercial item subject to the clause at 52.244-6, Subcontracts for Commercial Items, under a prime contract.

(k) The failure of the Contractor or subcontractor to comply in good faith with—

(1) The clause of this contract entitled "Utilization Of Small Business Concerns;" or

(2) An approved plan required by this clause, shall be a material breach of the contract.

(l) The Contractor shall submit ISRs and SSRs using the web-based eSRS at http://www.esrs.gov. Purchases from a corporation, company, or subdivision that is an affiliate of the prime Contractor or subcontractor are not included in these reports. Subcontract award data reported by prime Contractors and subcontractors shall be limited to awards made to their immediate next-tier subcontractors. Credit cannot be taken for awards made to lower tier subcontractors unless the Contractor or subcontractor has been designated to receive a small business or small disadvantaged business credit from an ANC or Indian tribe. Only subcontracts involving performance in the United States or its outlying areas should be included in these reports with the exception of subcontracts under a contract awarded by the State Department or any other agency that has statutory or regulatory authority to require subcontracting plans for subcontracts performed outside the United States and its outlying areas.

(1) *ISR*. This report is not required for commercial plans. The report is required for each contract containing an individual subcontract plan.

(i) The report shall be submitted semi-annually during contract performance for the periods ending March 31 and September 30. A report is also required for each contract within 30 days of contract completion. Reports are due 30 days after the close of each reporting period, unless otherwise directed by the Contracting Officer. Reports are required when due, regardless of whether there has been any subcontracting activity since the inception of the contract or the previous reporting period.

(ii) When a subcontracting plan contains separate goals for the basic contract and each option, as prescribed by FAR 19.704(c), the dollar goal inserted on this report shall be the sum of the base period through the current option; for example, for a report submitted after the second option is

exercised, the dollar goal would be the sum of the goals for the basic contract, the first option, and the second option.

(iii) The authority to acknowledge receipt or reject the ISR resides—

(A) In the case of the prime Contractor, with the Contracting Officer; and

(B) In the case of a subcontract with a subcontracting plan, with the entity that awarded the subcontract.

(2) *SSR*.

(i) Reports submitted under individual contract plans—

(A) This report encompasses all subcontracting under prime contracts and subcontracts with the awarding agency, regardless of the dollar value of the subcontracts.

(B) The report may be submitted on a corporate, company or subdivision (*e.g.* plant or division operating as a separate profit center) basis, unless otherwise directed by the agency.

(C) If a prime Contractor and/or subcontractor is performing work for more than one executive agency, a separate report shall be submitted to each executive agency covering only that agency's contracts, provided at least one of that agency's contracts is over $700,000 (over $1.5 million for construction of a public facility) and contains a subcontracting plan. For DoD, a consolidated report shall be submitted for all contracts awarded by military departments/agencies and/or subcontracts awarded by DoD prime Contractors. However, for construction and related maintenance and repair, a separate report shall be submitted for each DoD component.

(D) For DoD and NASA, the report shall be submitted semi-annually for the six months ending March 31 and the twelve months ending September 30. For civilian agencies, except NASA, it shall be submitted annually for the twelve month period ending September 30. Reports are due 30 days after the close of each reporting period.

(E) Subcontract awards that are related to work for more than one executive agency shall be appropriately allocated.

(F) The authority to acknowledge or reject SSRs in eSRS, including SSRs submitted by subcontractors with subcontracting plans, resides with the Government agency awarding the prime contracts unless stated otherwise in the contract.

(ii) Reports submitted under a commercial plan—

(A) The report shall include all subcontract awards under the commercial plan in effect during the Government's fiscal year.

(B) The report shall be submitted annually, within thirty days after the end of the Government's fiscal year.

(C) If a Contractor has a commercial plan and is performing work for more than one executive agency, the Contractor shall specify the percentage of dollars attributable to each agency from which contracts for commercial items were received.

(D) The authority to acknowledge or reject SSRs for commercial plans resides with the Contracting Officer who approved the commercial plan.

(End of Clause)

Alternate II (Oct 2001). As prescribed in 19.708(b)(1)(ii), substitute the following paragraph (c) for paragraph (c) of the basic clause:

(c) Proposals submitted in response to this solicitation shall include a subcontracting plan, that separately addresses subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. If the offeror is submitting an individual contract plan, the plan must separately address subcontracting with small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns with a separate part for the basic contract and separate parts for each option (if any). The plan shall be included in and made a part of the resultant contract. The subcontracting plan shall be negotiated within the time specified by the Contracting Officer. Failure to submit and negotiate a subcontracting plan shall make the offeror ineligible for award of a contract.

52.225-5 - Trade Agreements (Feb 2016)

(a) *Definitions.* As used in this clause --

“Caribbean Basin country end product”

(1) Means an article that—

(i)

(A) Is wholly the growth, product, or manufacture of a Caribbean Basin country; or

(B) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a Caribbean Basin country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed; and

(ii) Is not excluded from duty-free treatment for Caribbean countries under 19 U.S.C. 2703(b).

(A) For this reason, the following articles are not Caribbean Basin country end products:

(1) Tuna, prepared or preserved in any manner in airtight containers;

(2) Petroleum, or any product derived from petroleum;

(3) Watches and watch parts (including cases, bracelets, and straps) of whatever type including, but not limited to, mechanical, quartz digital, or quartz analog, if such watches or watch parts contain any material that is the product of any country to which

the Harmonized Tariff Schedule of the United States (HTSUS) column 2 rates of duty apply (*i.e.*, Afghanistan, Cuba, Laos, North Korea, and Vietnam); and

(4) Certain of the following: textiles and apparel articles; footwear, handbags, luggage, flat goods, work gloves, and leather wearing apparel; or handloomed, handmade, and folklore articles;

(B) Access to the HTSUS to determine duty-free status of articles of these types is available at http://www.usitc.gov/tata/hts/ . In particular, see the following:

(1) General Note 3(c), Products Eligible for Special Tariff treatment.

(2) General Note 17, Products of Countries Designated as Beneficiary Countries under the United States—Caribbean Basin Trade Partnership Act of 2000.

(3) Section XXII, Chapter 98, Subchapter II Articles Exported and Returned, Advanced or Improved Abroad, U.S. Note 7(b).

(4) Section XXII, Chapter 98, Subchapter XX Goods Eligible for Special Tariff Benefits under the United States—Caribbean Basin Trade Partnership Act; and

(2) Refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the acquisition, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

"Designated country" means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan (known in the World Trade Organization as "the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu (Chinese Taipei)"), or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

“Designated country end product” means a WTO GPA country end product, an FTA country end product, a least developed country end product, or a Caribbean Basin country end product.

“End product” means those articles, materials, and supplies to be acquired under the contract for public use.

“Free Trade Agreement country end product” means an article that--

(1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

“Least developed country end product” means an article that--

(1) Is wholly the growth, product, or manufacture of a least developed country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

“United States” means the 50 States, the District of Columbia, and outlying areas.

“U.S.-made end product” means an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

“WTO GPA country end product” means an article that--

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services, (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

(b) *Delivery of end products.* The Contracting Officer has determined that the WTO GPA and FTAs apply to this acquisition. Unless otherwise specified, these trade agreements apply to all items in the Schedule. The Contractor shall deliver under this contract only U.S.-made or designated country end products except to the extent that, in its offer, it specified delivery of other end products in the provision entitled “Trade Agreements Certificate.”

(End of clause)

Section J-List of Attachments

Attachments to HHSO100201600005I
Attachment 1 – Sample Invoice
Attachment 2 – BARDA Request for Shipment form
Attachment 3 – OIG Hotline Poster

Company Name

Invoice Sample

XXXXXXX

REMIT TO:
XXXXXX
XXXXXXXXX
XXXXXXXXXXX

Page
1

Invoice number
XXXXXXXX

Please indicate remittances and correspondence

Bill To:
Contracting POC
ASPR-AMCG-[POC Phone Number]
200 C Street SW
Washington, DC 20024

CORP TAX ID: XXXXXX
DUNS NUMBER: XXXXXX

Date of invoice	Contract Period of Performance		Your order number	F.O.B. point
XXXXX			Contract Number: XXXXXXX Task Order Number: XXXXXXX Requisition No. : XXXXXXX	SHIPPING
Carrier				Terms: Net 30

	Description		Quantity/Unit of Issue	Duration	Unit price	Extended Amount
CLIN000X	CLIN000X: Storage and Stability: Storage of XXXXX Bulk Lots		No. of lots	1 month January 2016	XXXX per lot per month	XXXXX
CLIN000X	CLIN 000X: Prior Contracts: Storage and Stability of Bulk Lots--XXXXX		No. of lots	1 month January 2016	XXXX per lot per month	XXXXX

BARDA REQUEST FOR SHIPMENT

BARDA Influenza Division Vaccine Request Form

Reason for Shipment: _____

Shipping Origin Location: _____

A. Vaccine Request

Agent Requested: _____

No. of Vials Requested: _____

Requester Signature: _____ Date: _____

Shipping Address:

B. Investigational Agent Shipment.

Complete the section below send with vaccine to shipping address listed above

Dosage Form: _____ Volume Per Vial: _____

No. of Vials Shipped: _____ Lot No.: _____ Shipment Date: _____

Shipment Conditions (Check all applicable boxes):

Cool Pack ☐ Temperature M ☐ r

_____ _____

Signature Date/Time Shipped

C. Investigational Agent Receipt Verification

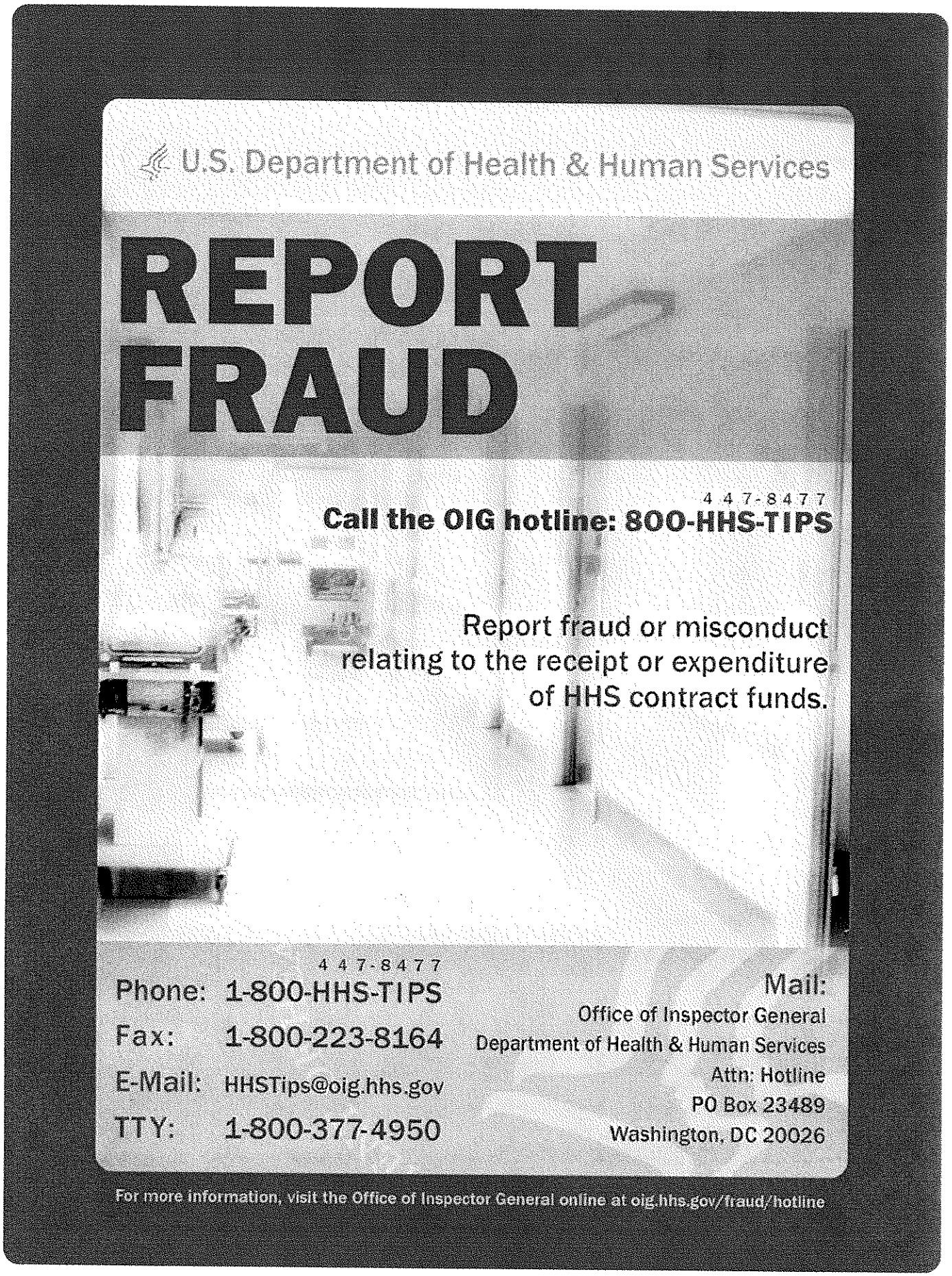
Complete the section below upon receipt and scan this form to BARDA ID (Attention: xxx.xxx@hhs.gov)

No. of Vials Received: _____ Temperature of Shipment Received: _____

Receipt Condition: Intact ☐ Damage ☐

_____ _____

Signature Date/Time of Receipt



Attachment 3